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**Managing or maintaining  
bias? Examining the  
conceptualisation of conflicts  
of interest in medical journal  
publishing**

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## **Declaration of originality:**

I, Rachel Alison Hendrick, hereby declare that the following thesis was composed by me. The work presented here is my own and has not been submitted for any other degree or professional qualification.

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Word count: 86,225



# Abstract

**BACKGROUND:** It has been claimed that the involvement of commercial companies in medical and health research poses risks relating to potential conflicts of interest. In response, many journals have developed conflict of interest policies, and there has been a proliferation of related guidance from publishers, professional associations and commercial companies, mostly centred on processes of voluntary disclosure. Studies and commentaries on these have raised concerns regarding the adequacy of such practices, but there has been limited analysis of the underlying context – *how* and *why* policies have been constructed in this way – or exploration of alternative approaches.

**AIM:** This thesis examines how actors within medical journal publishing conceptualise conflicts of interest. It analyses their understandings of conflicts of interest: which types of interest are deemed most significant; which actor groups are seen as conflicted; and how conflicts are managed. Through doing so, it explores the barriers to, and possibilities of, change.

**METHODS:** The study draws on two distinct sets of data. The first is a sample of conflict of interest policies and guidance. The second is 48 semi-structured interviews with actors working in a range of roles related to medical journal publishing. These data were thematically analysed to illustrate how medical journal publishing conceptualises and manages conflicts of interest, to identify perceived strengths and weaknesses of current approaches, and to identify potential opportunities for improvement.

**RESULTS:** There appears to be an established discourse around conflicts of interest, which emphasises particular stakeholders, while others, who also have opportunities to influence journal content, are frequently absent from the debate. Financial interests are readily highlighted, while non-financial ones receive less attention and are thus often unregulated (Chapter 5). High levels of

consistency characterise the ways in which actors discussed the management of conflicts of interest: for example, self-disclosure was regularly highlighted, despite the acknowledged weaknesses of this approach (Chapter 6). The existence of further mechanisms that offer the potential to assist in managing conflicts of interest were identified, though findings suggest that, in practice, these currently have limited uptake (Chapter 7). Interviewees' suggestions of how conflicts of interest might be better managed (e.g. through greater data transparency) are also analysed. Overall, narrow interpretations of conflicts of interest and their management appear to have become institutionalised in ways that serve to limit the uptake of alternative approaches.

**DISCUSSION:** Given the substantive importance that medical research can have on health policies and treatments, robust processes are required to protect the integrity and legitimacy of journals. This research shows that existing, institutionalised understandings of conflicts of interest have critical limitations, which leaves medical publishing open to potentially unethical practices that may be a source of bias in published evidence. This poses a significant threat to the desire to attain ethically robust, peer-reviewed medical/health research that can be used to inform policy and practice. Drawing on the interview data, the thesis explores some possible alternatives that may warrant further consideration.

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# Acronyms and abbreviations

## **Miscellaneous:**

AMA: American Medical Association

AMC: Academic Medical Centre

BAT: British American Tobacco

CMA: Canadian Medical Association

COIs: Conflicts of Interest

CRO: Clinical Research Organisation

CTP: Clinical Trial Protocol

CTR: Clinical Trial Registration

DI: Discursive Institutionalism

ESRC: Economic and Social Research Council

ETS: Environmental Tobacco Smoke

FDA: Food and Drugs Administration

GSK: GlaxoSmithKline

JCI: Journal Citation Index

JOC: Journal Oversight Committee

IF: Impact Factor

KOL: Key Opinion Leader

MPIP: Medical Publishing Insights and Practices

MWC: Medical Writing Companies

NIH: National Institute of Health

SKB: SmithKlineBeecham

URM: Universal Requirements for Manuscripts

## **Professional Associations:**

AMWA: American Medical Writers Association

COPE: Committee on Publication Ethics

CSE: Council of Science Editors

EMWA: European Medical Writers Association

ICMJE: International Committee of Medical Journal Editors

ISMPP: International Society of Medical Publishing Professionals

WAME: World Association of Medical Editors

### **Publishers:**

OUP: Oxford University Press

T&F: Taylor and Francis

### **Journals:**

AJC: American Journal of Cardiology

AJM: American Journal of Medicine

AJOG: American Journal of Obstetrics and Gynecology

Annals: Annals of Internal Medicine

BMJ: British Medical Journal

CMAJ: Canadian Medical Association Journal

IAOEH: International Archives of Occupational and Environmental Health

JAACAP: Journal of the American Academy of Child and Adolescent Psychiatry

JAMA: Journal of the American Medical Association

JCP: Journal of Clinical Psychology

JIM: Journal of Internal Medicine

JNCI: Journal of the National Cancer Institute

NEJM: New England Journal of Medicine

### **Interviewees**

A: Author

AE: Associate editor

EIC: Editor in chief

ME: Managing editor

MW: Medical writer

MPC: Medical publishing critic

P: Publisher

SE: Senior editor

# Definitions of key terms

## **Clinical Trial Registration**

The registration of clinical trials in a public trials registry.

## **Clinical Trial Protocols**

A document that provides details of how the trial will be conducted.

## **Ghost-writing/ghost authorship**

The practice of commissioning professional writers to help develop scientific articles, without declaring the involvement of such writers on the papers.

## **Guest authorship/honorary authorship**

Listing senior researchers as authors on papers, when in practice their involvement did not constitute authorship status. This is typically done to confer prestige to an article. Such researchers may receive payment from companies to be named used as authors.

## **Impact factor**

A measure reflecting the yearly average number of citations to recent articles published in a journal. The impact factor is the most commonly used method for determining a journal's importance in its field.

## **Journal Supplements**

Collections of articles discussing a particular topic that are published as either separate issues or part of a regular issue of a journal.

## **Key Opinion Leaders**

Physicians or researchers who are considered authorities in their field and may influence the prescribing behaviours of their peers. They may include

physicians, scientists or academics. Key Opinion Leaders may act as guest authors.

### **Open Access journals**

Scholarly journals that are available to readers without having to pay a fee. Costs are met through different ways; most commonly, the authors will pay to publish their articles with the journal.

### **Open data**

The making of anonymised clinical trial data publicly available, so that they can be subjected to independent scrutiny and reanalysed.

### **Peer review**

The process of critically appraising articles by other scholars or practitioners in the field, before publishing them in a journal.

### **Publication bias**

Basing publishing decisions on the outcome of a study: for example, failing to publish the results of negative studies, or publishing positive outcomes multiple times.

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# CHAPTER ONE: INTRODUCTION

## 1.1 Prologue

Conflicts of interest (COIs) in medical journal publishing rose to prominence as an issue of concern in the 1990s and 2000s, with worries over how they could potentially affect both research and publishing processes. The on-going public dispute regarding statins, described below, between two high profile journals – *The Lancet* and the *BMJ* – provides a clear example of the problems associated with the conflicting interests of actors involved in medical research and journal publishing. It highlights the contentious nature of debates about COIs, and demonstrates the fact that concerns about the adequacy of current mechanisms and procedures reach the upper echelons of medical publishing, and that they continue to be debated among key adopters and innovators of current best practice.

This very open disagreement highlights how various different actors may potentially have conflicts which could affect medical/health journals. The *BMJ* has argued that Rory Collins, head of the Cholesterol Treatment Trialists' (CTT) Collaboration and lead author of a review, published in *The Lancet*, on the evidence from clinical trials and observational studies involving statins (Collins et al., 2016), has a vested interest in the debate (Godlee, 2016). Collins and his colleagues, and the editor in chief of *The Lancet* (Richard Horton) have responded by criticising the fact that a key member of the professional association called in to investigate – the Committee on Publication Ethics (COPE) – had an acknowledged (though undisclosed) COI, but that they only recused themselves from investigations eight months after adjudicating on the submission and liaising with the subject (the *BMJ*) of the complaint, and determining the outcome of the review (Horton, 2016a, Armitage et al., 2016).

After two years of exchanges, COPE said that it would not act further,

stating that it is not a regulatory authority that can govern the practices of journals (Horton, 2016b), despite the fact that it does actively investigate complaints and offers advice to those making them (COPE, 2016a). The alleged inability of COPE to act, and the arbitrary nature of its investigations, demonstrates also the current lack of an independent organisation that can look into claims of research and publication misconduct within journals, and has the means of taking appropriate disciplinary action (Horton, 2016a).

This argument between *The Lancet* and the *BMJ* stems from the latter's concerns over the lack of access to data from clinical trials on statins. In their review, Collins et al. (2016) claimed that the *BMJ* had overstated the risks of the drugs. The *BMJ* responded to these criticisms by repeating calls for the data from statins trials to be made available for wider analysis (British Medical Journal, 2016d): if such data were made more widely accessible, it would increase the possibility of determining whether such risks were indeed over-emphasised, or whether the original reports did in fact misrepresent the findings. As Fiona Godlee, EIC of the *BMJ*, explained in a recent radio interview:

*'The trials do under-report adverse events. And in many of these Statins trials ... they were run in periods where people who experienced side effects were excluded. So, I think this review that was published in The Lancet yesterday, I think it overstates that particular case. ... There is very little new in this review. It's not independent, it's done by the trialists themselves ... marking their own homework. And no one else has seen the data apart from the trialists and the drug manufacturers. There's no methodology, it's not a systematic review ... And I think they've done much more to look at the benefits of Statins, well I know they've done more to look at the benefits than they have to look at the harms of treatment ... We want much more transparency in this debate than has been achieved so far.'* (BBC Radio 4, 2016).

This contentious debate illustrates how issues of COIs and access to trial data are interlinked. Data from studies are frequently not made available to others (Gøtzsche, 2011). If data were made available for further analysis, it would allow

the accuracy of the original results to be independently verified, and would help to determine whether or not the potential COIs of the actors involved in the initial studies had affected the outcomes. As it stands, the data regarding statins, and any limitations of the original study, cannot be checked. It may be that the analysis is indeed an accurate representation of the data: providing access to that data for secondary analyses would alleviate worries and ensure that informed choices could be made about the best course of treatment to follow (Krumholz, 2016, Lehman, 2016).

This thesis aims to examine how COIs are conceptualised in medical journal publishing: which groups of actors are understood to have potential conflicts that require management, what types of interests may cause these conflicts, and how it is felt that they should be handled. In doing so, it looks at whether these existing perceptions help to prevent resulting COIs from affecting the medical/health research literature, or instead enable them. The statins debate cited above illustrates the ways in which COIs can potentially affect a range of actors within medical journal publishing, including authors, journal editors, and those sitting on the boards of professional associations that have some degree of responsibility for investigating allegations of malpractice. It demonstrates the weaknesses of a key professional publishing association (COPE), which is heavily relied upon in this regard, and as such, it points more broadly to the deficiencies in existing processes of management. It also highlights the possible impact such COIs can have on public health, such as the confusion that has ensued over whether or not statins are indeed efficacious or instead a risk to people at low risk of cardiovascular disease.

The ways in which the commercial funding of research can impact on medical/health journals is heavily focused on in the literature on COIs. In particular, the potential conflicts that can arise from the relationships of academic researchers with the pharmaceutical and tobacco industries have been highly contested and debated, with the literature more developed on these than other commercial manufacturing industries. As such, I focused on these two



industries in my research when considering the COIs that can arise from connections with this sector. It is also particularly interesting to compare the very different regulatory approaches that have been developed in medical journal publishing to manage the COIs that arise from the involvement of these two industries.

## **1.2 Contextual background: The rise of conflicts of interest in medical research**

Partnerships between the pharmaceutical industry, academic researchers and government can be beneficial, with each bringing different skills and resources to the table, allowing new medicines to be developed (Lo and Field, 2009, Rule and Shamoo, 1997, Duvall, 2006, Bodenheimer, 2000). Academic and government researchers, doing basic science, can identify new potential targets for drugs and new strategies for treatment, as well as targeting therapies at patients who will most benefit from them, while avoiding particular treatments for patients who are at high risk of adverse side effects. The pharmaceutical industry has good manufacturing processes, experience with drug approval processes and, critically, the finance to develop drugs (Lo and Field, 2009). However COIs can occur when the interests of private gain clash with the two key values of medical ethics: beneficence (the primary responsibility to patients and research participants) and nonmaleficence (ensuring the least harm possible to achieve a beneficial outcome) (Rule and Shamoo, 1997). As such, they have been identified by some authors as presenting a potential concern in medical and health research (Solyom, 2004).

COIs arising from collaborations between researchers and the tobacco industry have been an area of concern since the 1950s, with tobacco setting the groundwork for the problem of COIs as we understand it: arguably, the steps taken to form relationships with scientific researchers have informed other commercial industries' approaches to shaping scientific and medical research (Brandt, 2012, White and Bero, 2010). In attempting to discredit the scientific

evidence around the dangers of smoking, the tobacco industry sought to take control of science, influencing and engineering it to produce results that supported its aims (Brandt, 2012). Prior to this period, there was a general perception that scientific practice was immune to influence from external pressures (ibid). However, faced with increasing evidence regarding the dangers of smoking, the tobacco industry began to exert control over the production of scientific knowledge, building an alliance of powerful interests and influence. The industry worked to present itself as being supportive of science, developing relationships with scientists who were sceptical of the links between smoking and disease, and calling for the need for more research, which it offered to fund (ibid). It also manufactured doubt regarding scientific evidence that was unfavourable to it (ibid). The industry set up research committees (such as the Tobacco Industry Research Committee and the Center for Indoor Air Research), which portrayed themselves as independent organisations, yet they allowed tobacco companies to wield control over the research they funded (Brandt, 2012, Bero, 2005, Drope and Chapman, 2001, Barnes and Bero, 1996). These committees reviewed proposals and sponsored academic researchers who were sympathetic to the industry.

The problem of COIs in medical and health research, resulting from pharmaceutical industry involvement, came to the fore in the 1980s (see Korn, 2000, Sharpe, 2002, Resnik, 2000, Warner and Gluck, 2003, Thompson, 1993, Healy, 2004, Etzkowitz, 1990, Etzkowitz, 1989). This reflected concerns over the pharmaceutical industry's increased funding of research and development (R&D), which rose in the U.S. from US\$2 billion per year in 1980 to US\$16 billion per year in 1990 (Resnik, 2000), while spending from the federal government fell. This growth in pharmaceutical funding on R&D was accompanied by laws that strengthened intellectual property rights, such as the Bayh-Dole Act in the U.S. in 1980, which enabled academics and institutions to apply for patents on their research and thus directly profit from it financially (Korn, 2000, Lo and Field, 2009, Sharpe, 2002). These laws provided incentives for clinicians, academic institutions and researchers to form partnerships with companies.

This encouraged cooperation between industry, government and academia, but has also been depicted as having fundamentally altered the system of academic research by transforming it into a commercial enterprise (Krimsky, 2010). In the 10 years that followed the Bayh-Dole Act, the number of university-industry partnerships doubled in the US, with roughly 1000 university-industry research centres being established at over 200 universities (Krimsky, 2003). By 2002, 70 per cent of funding for clinical trials came from industry (Sharpe, 2002). The introduction of financial incentives (for both individuals and institutions) has been seen by some commentators as having a negative impact upon the ethical climate of academic medicine (e.g. Solyom, 2004, Angell, 2000, Resnik and Shamoo, 2002, Bodenheimer, 2000, Rule and Shamoo, 1997), potentially limiting cooperation between researchers, departments and institutions, and delaying or hindering the publication of results (Krimsky, 2010).

A new research model also emerged in the 1980s and 1990s: the pharmaceutical industry began to shift its funding from Academic Medical Centres (AMCs) to Contract Research Organisations (CROs), which conducted all stages of the industry's clinical trials (Bodenheimer, 2000). It is estimated that in the U.S. funding to the former dropped from 80 per cent in 1991 to 40 per cent in 1998, while the CRO market size rose from US\$1 billion in 1992 to US\$7.9 billion in 2001 (Mirowski and Van Horn, 2005). These private companies offered increased efficiency and cost-savings by employing researchers who were willing to focus on tailoring their work to meet regulatory requirements, and could work faster than their academic counterparts. They also allowed the pharmaceutical companies to retain more control over their trials – both in designing and analysing the data – and the resulting publications (Bodenheimer, 2000). In an attempt to win back pharmaceutical business, AMCs began to offer more control of the research to industry, allowing it to design trials, analyse the data and control the publication of resulting articles (Angell, 2008, Angell and Relman, 2002, Lenzer, 2008).

It can be legitimate for researchers to have secondary interests and indeed, they are often unavoidable. Further, as stated at the start of this section, collaborations between the pharmaceutical industry and academia can be beneficial to the advancement of medicine and ultimately in improving public health: new and improved treatments may be developed as a result of such collaborations (Duvall, 2006, Lo and Field, 2009). Lo and Field (2009) cite as an example the therapies that were developed to treat HIV as a result of partnerships between academia and the pharmaceutical industry, which transformed a previously fatal illness into a chronic disease that people are now able to live with. However, problems can occur if secondary interests take priority over primary ones, which may affect actors' ability to effectively protect research participants or conduct research impartially. The latter could potentially lead to biased results, and consequently inaccurate evaluations of the effectiveness of treatments (Warner and Gluck, 2003). These risks have the potential to undermine trust in the research enterprise (ibid).

This increased commercialisation of medical research, which has seen biomedical researchers and physicians working with private companies, has thus led to a greater potential for COIs to arise. Physicians' professional primary interest is to provide beneficial patient care, and researchers' main objective is to conduct valid research, with the aim of generating and disseminating knowledge and improving public health (Hurst and Mauron, 2008). While one of the primary goals of pharmaceutical companies' is to develop products that improve health, their ultimate fiduciary responsibility as for-profit organisations is to ensure revenue-maximisation for their shareholders (Brennan et al., 2006, Wiist, 2010, Hurst and Mauron, 2008, Resnik, 2000). Hastings (2013) notes that this generates a cause for concern: business will always come before the social cost. This research will explore how COIs might occur when for-profit manufacturing companies fund independent medical/health researchers, with the researchers potentially being confronted by secondary interests that arise from a sense of obligation towards their for-profit sponsors.

Manufacturing sector companies' funding of medical/health research is not the only potential cause of conflicting interests. Funding from the third sector, or government, also has the possibility of leading to conflicts (Smith, 2010, Dreger, 2015). Personal gain, either financial (such as through shareholdings, consulting fees, or intellectual property interests), or other, non-financial interests (for example, prestige and career advancement), may also present researchers with secondary interests that conflict with their primary ones (Hurst and Mauron, Johnston 2010, Resnik 2000). Literature in the sociology of science has looked further at the difficulties of separating the scientific process from other intellectual activities, such as political beliefs (e.g. Gieyrn, 1983).

The potential impact of COIs on medical/health publications has become a topic of concern. Journals have responded by developing policies which attempt to manage COIs. A series of high profile lawsuits against pharmaceutical companies in the 2000s, and the consequential disclosure of internal industry documents (UCSF Library and Center for Knowledge Management, 2005), give a concrete insight into the various ethically questionable ways in which journals have at times been used by such companies to promote their products, including the selective reporting of results (e.g. Ross et al., 2008, Vedula et al., 2009, Vedula et al., 2013, Vedula et al., 2012, Fugh-Berman, 2010, Krumholz et al., 2011, Jureidini et al., 2008, Steinman et al., 2006). This can be done, for example, through multiple publication of positive results (Lexchin et al., 2003, Melander et al., 2003, Johansen and Gøtzsche, 1999) or suppressing the publication of negative studies (Lexchin et al., 2003, Schott et al., 2010, Ross et al., 2009). This is referred to as 'publication bias' (Dickersin, 1990, Ross et al., 2012). Tobacco industry documents, also released in litigation (UCSF Library and Center for Knowledge Management, 2002), have shown that this industry has employed similar practices (Rampton and Stauber, 2002, Bero et al., 1994).

### 1.3 Research aim

This thesis seeks to explore understandings within the institutional environment of medical journal publishing of what can lead to COIs. It also interrogates how effective the current methods of managing them are, and whether it is possible to improve these and thus enhance the integrity of the medical/health literature. To explore this, the following primary research question was developed:

- 1) *To what extent does the institutional environment of medical journal publishing inform actors' conceptualisation and management of COIs and their consideration of alternative approaches?*

I was particularly interested in how actors within the institutional environment conceptualise COIs (who might have conflicts that require management, and what types of interest or relationship can pose a conflict), the impact of these understandings on the management of COIs, and exploring other potential solutions. Three further subsidiary questions were therefore developed:

- i. *How do actors within the medical journal publishing industry conceptualise COIs?*
- ii. *What are the implications of this conceptualisation on the effective management of COIs?*
- iii. *What alternative or additional systems could be employed to further manage COIs, and what appear to be the barriers to their implementation?*

By exploring the very conceptualisation of COI within the medical journal publishing institutional environment, and how and why current existing mechanisms to manage them have developed, it is hoped that the barriers to, and possibilities of, improving them might be better understood.

Before proceeding with this thesis, it is important to summarise here why COIs are understood to be problematic, in the context of this PhD. This research takes a normative approach towards the research topic with regards to what the perceived purpose of medical/health journals is, and how and why COIs can threaten that. Scientific research, and the peer reviewed journals that present the results of it, helps to inform health policy and practice. As such, the veracity

of the research and publication processes is imperative. However, it is assumed that, by their very nature, COIs put at risk the independent judgement of those who have them and thus their ability to remain neutral (see Chapter Two, Section 2.2 for more on the definition of COIs). This means that the evidence they present, upon which public health decisions may be made, is potentially biased and possibly incorrect. For example, research sponsored by Roche, which was published in peer-reviewed papers in well-respected medical journals (e.g. Nicholson et al., 2000, Treanor et al., 2000, Kaiser et al., 2003), overstated the benefits of the company's drug Oseltamivir (Tamiflu) and down-played the risks (Kumar Gupta et al., 2015). However, a Cochrane Systematic Review (updated in 2016) found that the drug in actual fact increased the risk of nausea, vomiting and psychiatric events in adults, and vomiting in children, and that it had no protective effect on mortality on patients with 2009A/H1N1 influenza (Heneghan et al., 2016). Yet Tamiflu had already earned Roche over US\$18bn/£11bn in sales for the company since 1999, with the U.K. government stockpiling 65 million treatments for a cost of US\$1.3bn (Abbasi, 2014). This example therefore demonstrates how COIs can result in inaccurate research and reporting, which in turn can ultimately lead to incorrect policy decisions and practices being made.

COIs also bring the credibility of the evidence they present into jeopardy and threaten trust in the medical research process and its results more generally (Lo and Field, 2009). A loss of trust in medical research and publishing is extremely problematic (and even dangerous) as it will leave policy-makers, prescribers and the public uncertain with regards to making medical decisions. An example of a loss in trust is in the case of Andrew Wakefield and his 1998 article in *The Lancet* (2014), which contended that the Measles, Mumps and Rubella (MMR) vaccination was linked to autism. It transpired that Wakefield had, in fact, undisclosed COIs, with his research being funded by personal-injury lawyers whose clients were suing the MMR vaccine-makers (Editorial, 2008, Godlee, 2011b). However, although his claims have been thoroughly debunked, the fallout has lived on, with a lingering distrust by some of the public in medical

research; this has led to, for example, outbreaks of measles amongst children whose parents refused to vaccinate them, and resulted in deaths (Eisenstein, 2015).

Trust is thus crucial in medicine: it is important for the public to have faith in those involved in medical research, and for the latter to themselves be deserving of that trust (Brody, 2007). Lo et al. argue that the purpose of COI policies is ‘maintaining the integrity of professional judgment and sustaining public confidence in that judgment’ (2009, p. 49). As discussed above, COIs threaten the integrity of medical research and its representation in peer reviewed journals, and thus reduce trust in the enterprise as a whole. It is therefore crucial to have effective policies and processes in place to manage potential or real COIs, to both prevent (or at least limit) the likelihood of their impacting negatively on the journal literature, as well as to help restore confidence in it.

## **1.4 Thesis structure**

Following on from this introduction, Chapter Two introduces the reader to the literature directly relevant to this thesis, providing the context within which this study is placed and demonstrating the gap it fills. It offers an overview of both the theoretical literature on COIs and their management that has developed within social science disciplines, such as psychology, business, law and sociology, as well as articles written on COIs and their regulation in the area of medical/health research and journal publishing. It also provides a summary of key studies that have been conducted on the ways in which commercial companies have influenced the medical/health literature; the journals cited in these studies form my ‘contentious cases’ sample, as discussed in Chapter Four. The final section of Chapter Two looks at literature surrounding the disclosure of COIs, and gives an overview of existing studies that have been conducted on journals’ policies on this.



The 'institutional environment' (Furusten, 2013) of medical journal publishing is mapped out in Chapter Three. This offers readers a summary of the key actors, both organisational and individual, in order to set the context for the rest of the thesis, and to clarify the different stakeholders that are referred to throughout. It also offers a summary of the guidance provided by the organisations that comprise part of my data sample (further discussion on this is given in Chapter Four).

Chapter Four outlines the qualitative methodological approach taken to this research, with reflections on this process. A description is given of the research strategy, with the epistemological stance of critical realism outlined and an explanation given as to why it is particularly applicable to the primary research question outlined above. The data sample is then discussed: this comprised both documents (in the form of COI policies and guidance from my sample organisations) and the transcripts from 48 semi-structured interviews with individual actors working within the institutional environment of medical journal publishing. The sampling method and analytical approach (thematic analysis) are also described. Finally, an overview is given of the process of writing up the thesis.

My results are then set out in Chapters Five, Six and Seven. Chapter Five examines how actors within the institutional environment of medical journal publishing conceptualise COIs: which actors are understood to potentially have conflicts that could affect the content of medical journals and as such require management, and what types of interest are considered to potentially pose a conflict. Chapter Six looks at the primary method of managing COIs, while Chapter Seven examines existing and potential additional mechanisms that can assist in the management of COIs.

Chapter Eight proceeds to provide a more theoretically-informed reflection on the results. Employing theories of institutionalism (e.g. Mahoney and Thelen, 2010, Scott, 2014, Peters, 2012, Tolbert and Zucker, 1996, Furusten,

2013, Oliver, 1992, Dacin et al., 2002, Schmidt, 2008b, Schmidt, 2010b, Schmidt, 2010c, Schmidt, 2008a, Schmidt, 2010a), it explores how ideas surrounding COIs have developed and become established within the institutional environment of medical journal publishing, and the possibility of institutional change. The chapter continues by presenting suggestions, that emerged through analysis of the data, of areas where change might occur. The chapter finishes by suggesting two ideas that are worthy of further research.



# **Chapter Two: Literature Review**

## **Conflicts of interest in medical/health research and journals**

### **2.1 Introduction**

Having outlined the broad focus and research questions in Chapter One of this PhD, the following chapter outlines the literature of relevance to this project. Databases from both the social sciences and medical fields were searched: Web of Science, PubMed Central, Biomed Central, Medline, Science Direct, IBSS, JSTOR, USE and SCOPUS. Searches were carried out on combinations of terms central to the topic. Reference-mining was also undertaken, whereby further relevant papers were identified in those articles that had emerged from the database searches, thus ensuring that other relevant articles, not captured by the searches, were included. The extent of existing literature on the topic of conflicts of interest (COIs) in medical research and journals is vast, and this chapter does not represent a comprehensive, systematic review. Instead, it aims to outline debates within the literature regarding the significance of COIs and the adequacy of their management.

This chapter examines: a) the theoretical literature on COIs and their management that has been developed within social science disciplines (such as psychology, business, law and sociology); and b) the articles written on COIs and their regulation in the area of medical/health research and journal publishing. In doing so, it provides an account of the emergence of concerns surrounding COIs in medical research, their impact on the peer reviewed medical/health journal literature, and outlines recent debates regarding processes for their management. This chapter thus provides readers with the background through which to contextualise the work of the thesis.

The following section of this chapter (2.2) explores the key debates that have emerged in attempting to define COIs and concerns regarding resulting bias, and considers why they are deemed problematic. While there is some general agreement in terms of an overarching definition of COIs, scholars' opinions differ regarding the details, such as what types of interests can pose conflicts. Friedman (1992) argues that difficulties in reaching a consensus arise from problems with semantics, and while scholars generally concur that COIs are problematic, as this section demonstrates, pinpointing exactly why is a more complex task.

Section 2.3.1 examines which actors the literature focuses on as having potential biases that could impact on medical/health journals, and how these conflicts might arise. The focus is on researchers/authors, and several examples of authors with undisclosed ties to industry are given, highlighting the problematic nature of such relationships. To a slightly lesser extent, the potential conflicts of journal editors and owners are also looked at in the literature, and this section discusses several cases involving the firing of editors from their positions at high profile journals as a result of conflicts that arose with their journal owners; these illustrate the difficult positions editors can find themselves in. The potential conflicts of reviewers were discussed in only a minority of the papers reviewed.

Section 2.3.2 looks at how COIs can affect the outcome of clinical research: through the design of trials, particular results can be achieved, in ways that can have an effect on journals. Finally, Section 2.3.3 discusses publication bias: how publication decisions can be affected by the COIs involved in medical/health journal publishing. The focus of the literature on this topic is on the engagement in such practices of researchers who are commercially sponsored. As the principal funder of medical/health research, the pharmaceutical industry is the main focus, but studies of the tobacco industry show that it too has employed similar practices. Importantly, some studies show that researchers who are not

funded by industry can also have conflicts, which may bias their research and resulting publications.

Industry documents released during litigation, involving both the pharmaceutical and tobacco industries and medical/health journals, have offered insights into how these industries have engaged in the practices described in this chapter, and Section 2.4 looks at studies that have been conducted on such cases. The practices described here are: the use of ghost-writers; failure to disclose industry funding of research on resulting journal articles; and deliberately hiding and misconstruing data.<sup>1</sup>

The primary method generally employed for managing COIs is disclosure. The literature explored in Section 2.5.1 is, in large part, from the social sciences as it is in these fields that studies on these practices have been principally conducted. This section examines debates on the effectiveness of such practices: their strengths and weaknesses. The discussion of disclosure continues in Section 2.5.2 by relating it specifically to medical journals, and provides an overview of the studies that have been conducted to date on COIs and disclosure policies in such journals. These all employ different methods and selection criteria, but offer some practical insights into the weaknesses of current disclosure policies.

## **2.2 Defining conflicts of interest**

When searching the databases for literature on the definition of COIs, it became apparent that it is a relatively recent concept: in his brief overview of the emergence of the term, Luebke (1987) found no use of it at all before the 1930s and no use of it in a court case before 1949, when it was used in a case on a complex bankruptcy reorganization of one of the world's most valuable office properties, with attorneys taking steps to 'avoid conflicts of interest' (Foster,

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<sup>1</sup> The journals involved in these case studies will be used in the data sample of contentious cases, outlined in Chapter Four, Section 4.4.1.1.

2003). According to Luebke (1987), it was first used in an English dictionary in 1971, and it began to be used in professional codes of ethics in the 1970s. Since then, debate has arisen in various disciplines, ranging from psychology, business studies and sociology, over the nature of COIs, their influence on professions such as law, business and medicine, and how they should best be managed. These have included various attempts to define what COIs are, and to explore why they are problematic. A general and widely cited definition in the context of medical research is given by Thompson, who describes COIs as being ‘a set of conditions in which professional judgment concerning a primary interest ... tends to be unduly influenced by a secondary influence’ (1993, p. 573). Lo and Field offer a similar definition of COIs in their report on COIs in medical research: ‘A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest’ (Lo and Field, 2009, p. 46).

However, there is a lack of agreement amongst COI scholars, including those within the field of medical research over what constitutes a relevant ‘interest’ that requires management. Luebke (1987, 1993), who considers ‘interests’ to be situational – that is, they can be objectively determined – refers only to ‘material interests’ (i.e. financial) as having the potential to conflict with professional ones. According to him, broadening the understanding of what constitutes an ‘interest’ weakens the application of this term, and the focus should therefore be on financial interests only, rather than including non-financial ones. However, other scholars such as Schmidt argue that, as the world is not directly observable, actors may not be certain as to how best to achieve their interests, or indeed what those interests necessarily are: they are not only based upon utilitarian concerns (Schmidt, 2008b). Thus, other interests besides financial ones should arguably be taken into account (Marcovitch et al., 2010). Davis (1982, 1993) and Friedman (1992) agree, arguing that ‘interests’ encompass all those influences that can affect one’s judgement; focusing only on financial ones reduces our understanding of what can lead researchers to be biased. They argue that non-financial interests and relationships can also pose

conflicts and potentially lead to bias. Woll (2008) too argues that actors are not necessarily only driven by economic interests. Her case studies show that firm behaviour and goals that actors pursue are socially embedded, and that they may have other interests besides commercial ones that could influence their behaviour: policies which may help one area of business may hurt another.

## **2.3 Conflicts of interest in medical and health journals**

### ***2.3.1 Whose conflicts of interest can affect the journals?***

There are various actor groups involved in the publication of medical and health journals. The following section looks at the literature to explore who is perceived to have COIs, and how these are understood to potentially impact on those publications. As this section shows, the focus in the literature is primarily on researchers'/authors' COIs, with some discussion also regarding those of editors, and a limited amount on those of reviewers.

#### ***2.3.1.1 Researchers/authors***

Scientists conducting research and writing medical articles – both those employed by industry and those working in academia – may have COIs (both financial and other) which could potentially have an impact on their work, affecting the design and conduct of their studies, and also the reporting of them. Researchers who, inter alia, are in receipt of funding from a manufacturing sector company, have personal investments in companies, sit on companies' scientific advisory boards, or hold patents, can be seen as having potential COIs (Krimsky, 2004, Resnik, 2000). A 1998 study found that of 1105 university authors (first and last cited) whose 789 articles published in 1992 appeared in 14 journals, 34 per cent had at least one lead author with a financial interest in the subject matter under discussion (Krimsky, 2009, Krimsky, 2004). Another study found that authors whose work supported the safety of calcium-channel antagonists were more likely to have financial relationships with the developers of the drugs than those whose work did not support those drugs (Stelfox et al., 1998). Studies



have demonstrated that COIs arising from financial ties have an influence on biomedical research, affecting the conclusions of articles (Smith, 1998, Barnes and Bero, 1996, Gross et al., 2003). There is evidence that researchers with financial links to the tobacco and pharmaceutical industries are more likely to either downplay the risks or overstate the benefits of products in the publications they write (Barnes and Bero, 1996, Stelfox et al., 1998, Sharpe, 2002, Bekelman et al., 2003). It has also been demonstrated that, the results of studies funded by industry are more likely to produce outcomes favourable to it than studies funded by other sources (Lexchin et al., 2003, Cho and Bero, 1996, Friedberg et al., 1999).

In the U.S., between 2004 and 2010, Senator Grassley conducted a number of Congressional investigations into undisclosed relationships between academic researchers and physicians, and pharmaceutical and medical device companies; this paved the way for the Physician Payments Sunshine Act, requiring that drug and device manufacturers disclose payments over US\$100 made annually to physicians and teaching hospitals (Chimonas et al., 2012). Amongst the cases uncovered by Senator Grassley's was that of Charles Nemeroff. In 2002, Nemeroff published a review paper in *Nature Neuroscience* arguing: 1) for the use of a transdermal patch for the delivery of lithium for patients with depression; 2) that the emerging aspects of the neuroscience of mood disorders suggested that mifepristone might be a useful treatment of psychotic depression; and 3) that milnacipran might be helpful to treat fibromyalgia.<sup>2</sup> He failed to disclose on this paper that he held a patent on such a transdermal patch, that he was a member of the Scientific Advisory Board of Corcept Therapeutics who were conducting trials on mifepristone, or that he was Director and Chairman of the Psychopharmacology Advisory Board of Cypress Bioscience which wanted to bring milnacipran to the U.S. market to treat fibromyalgia (Healy, 2004). Another more recent high profile case involving an author with undisclosed relationships with industry was that of Charles Denham,

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<sup>2</sup> A long-term medical condition characterised by chronic pain all over the body.

who became editor of the *Journal of Patient Safety* in 2011. In December 2014, an editorial in the journal announced that Denham had COIs and had used the journal to promote those interests (Wu et al., 2014). Denham authored 10 articles in his journal, nine of which contained statements that could be linked to potential COIs. In five of these articles, no conflicts were declared, while in some, a conflict was mentioned in the disclosure form but not on the article itself (Dyer, 2014).

#### *2.3.1.2 Journal editors and owners*

Journal editors and owners face professional financial pressures (for example, to have a profitable journal), and there is therefore an incentive for them to produce reprints and supplements (see section 2.4.3) as they are large and valuable sources of income for them (Marcovitch, 2010, Lexchin and Light, 2006, Lundh et al., 2010, Elliott and Landa, 2010, Smith, 2006). Journal supplements are collections of articles discussing a particular topic, and are published as either separate issues or part of a regular issue of a journal (ICMJE, 2016). According to Lexchin and Light (2006), they often discuss a single drug, and are generally developed out of talks given at symposia sponsored by companies. For example, in 2003, GlaxoSmithKline sponsored, with an ‘unrestricted educational grant’, a supplement entitled ‘Advancing the Treatment of Mood and Anxiety Disorders: The First 10 Years’ Experience with Paroxetine’ in the journal *Psychopharmacology Bulletin* (edited by Charles Nemeroff). The papers in this supplement featured Key Opinion Leaders (KOLs) in psychiatry – those who are considered influential leaders in their field. There is no statement declaring GSK’s role (McHenry, 2010). Supplements are frequently not peer reviewed (Bero et al., 1992), yet they bear the parent journal’s name, and can thus be used as a marketing product (Rochon et al., 1994a, Cho and Bero, 1996). The lack of peer review may help to explain the lower standards seen in articles produced in these publications than of those published in the parent journals (Lexchin and Light, 2006): a comparison of articles published in non-peer-reviewed journals shows that the scientific quality of the former is lower with, for example, the

methodological sections of randomised controlled trials in such publications being of inferior quality to those published in the latter (Rochon et al., 1994a, Cho and Bero, 1996). Supplements are more likely to favour the sponsor's product and contain promotional content, and industry funding is also less likely to be acknowledged (Bero et al., 1992, Lexchin et al., 2003, Rochon et al., 1994a, Cho and Bero, 1996, Barnes and Bero, 1997). Journals can make substantial sums of money from supplements (Smith, 2003) – for example, US\$50,000 was charged by CHEST for up to a 60 page supplement in 2000 (Block, 2000) – and some journals are financially dependent upon them (Elliott and Landa, 2010). A survey conducted in 1992 found that 23 per cent of responding editors said that financial gain was the main reason they published supplements, and six out of 20 said that more than six per cent of their revenue derived from these types of publications (Bero et al., 1992). Citrome recommends peer-reviewing articles in supplements as a solution to this problem, and indeed, some journals do already require this (Citrome, 2010). However, Smith argues that, since the appeal to the pharmaceutical industry of supplements is the fact that they concentrate on one drug in a generally promotional way, an insistence on this by journals will not be so profitable (2003), so they will be unlikely to adopt such a policy. Some journals, such as *The Lancet* have decided that to publish supplements at all would signify too great an alliance with commercial interests, and that the quality of most articles appearing in supplements would not pass a peer-review process (The Lancet, 2010). Other journals published by *The Lancet's* publisher, Elsevier, however, do still publish them.

Articles sponsored by manufacturing sector companies may be reprinted and distributed freely to prescribers in the form of 'reprints' (Smith, 2005). While many individuals and organisations may request reprints, high reprint orders are associated with articles of research funded by the pharmaceutical industry (Handel et al., 2012). Such companies will sometimes spend US\$1 million on reprints of a single study that they have funded, as they know that they will reach a large audience (Smith, 2003, Lexchin and Light, 2006). Sales representatives were encouraged to give out reprints of the controversial ghost-

written article on Study 329 regarding GlaxoSmithKline's antidepressant Paxil (Jureidini and McHenry, 2011). Reprint sales from companies generate a great amount of revenue, which many journals rely on (Moynihan, 2003a, Moynihan, 2003b, Smith, 2003, Lundh et al., 2010), though it is hard to know exact amounts, as journals are often reluctant to release this information (Marcovitch, 2010). They have also been shown to boost citations, thus improving a journal's IF (Lundh et al., 2010). Reliance on reprints may thus constitute a COI for the journals involved, which may be more willing to accept articles of industry-funded research that are likely to be reprinted (Handel et al., 2012). Charles Nemeroff, discussed above, was lead author on an article published in 2006 in the journal *Neuropsychopharmacology* (of which he was also the editor). This article described positively a medical device by Cyberonics Company (Nemeroff et al., 2006); Nemeroff was also the head of Cyberonics' advisory board. Cyberonics ordered 10,000 reprints of the article (McHenry, 2010).

Advertising revenue is also important to journals, and as such editors may be reluctant to publish articles critical of the pharmaceutical industry, for fear of this being withdrawn (Lexchin and Light, 2006). While income from advertising allows journals such as the *British Medical Journal* and the *New England Journal of Medicine* to be provided free of charge to doctors (Smith, 2003), it can also pose another financial COIs for journal editors and owners (or their marketing departments) (Glassman et al., 1999). Glassman et al.'s 1999 study found that, out of six organisations surveyed that owned at least one journal, five raised 10 per cent or more of their total annual revenue through advertising in a single journal, and four of them raised almost as much revenue from drug advertisements as they did from membership fees and other assessments. This heavy reliance on advertising means that journal owners and editors may be reluctant to publish articles that are critical of the products produced by those companies buying advertising space. For example, in 2004, *Dialysis and Transplantation's* marketing department requested the rejection of an article because it was concerned about losing advertising (Dyer, 2004).

There have been several instances, at high profile journals, of editors being fired by the journal owners because of conflicts between the two parties' interests. In 1992, a paper published in *Annals of Internal Medicine* by Michael Wilkes, with an accompanying editorial by the journal editors, critically examined the scientific accuracy of drug advertisements in 10 leading medical journals. The journal subsequently lost \$1.5 million in advertising revenue. This led to tension between the editors, Robert and Suzanne Fletcher, and the journal's publisher, the American College of Physicians, and ultimately the Fletchers' resignation in 1993 (Tsai, 2003, Weerasinghe, 2009, Willinsky et al., 2007, Lexchin and Light, 2006). In 1999, the editor for 17 years of *JAMA*, George Lundberg, was fired; this coincided with his publication of an article on what constitutes sex at the same time as President Clinton's impeachment trial (Hopkins, 1999, Willinsky et al., 2007). The journal's publishers, the American Medical Association (AMA), said it was because he had lost their confidence and trust in his ability to maintain the journal's integrity, but it was widely considered that it was due to his publication of an article with charged political implications (Tsai, 2003): Lundberg's interest in what the journal should publish conflicted with the AMA's interests regarding how the journal was perceived in the political climate of the time. Also in 1999, Jerry Kassirer was forced to resign as editor in chief from the *NEJM* by the journal's owners, allegedly after he refused to exploit the journal's name and logo for spin-off, commercially-lucrative publications (Mitka, 1999, Tsai, 2003); while this was not an issue of editorial independence over journal content, it highlights how the agendas of journal editors and owners can differ, with scientific responsibility conflicting with commercialism. Kassirer was replaced by Jeffrey Drazen who had a history of strong ties with the pharmaceutical industry (Willinsky et al., 2007, Charatan, 2000) (see Chapter Six, Section 6.3.2 for more on this). In 2006, the Canadian Medical Association (CMA) sacked its journal's (the *CMAJ*) editor, John Hoey, and Senior Deputy Editor, Anne Marie Todkill. The CMA had applied pressure on the editors regarding articles over several years (Hoey, 2006, Willinsky et al., 2007). In December 2005, the journal published an article on how Canadian pharmacists were invasively questioning women who were seeking to purchase

the over-the-counter emergency contraception drug, known as Plan B. Prior to its publication, the CMA made certain demands regarding editing of the paper; Hoey and Todkill responded by writing an editorial which raised concerns about the editorial autonomy of the journal (Willinsky et al., 2007). In February 2006, the editors again faced pressure from the Association to water down articles critical of Health Minister Tony Clement; they were fired later that month. As with the case of Lundberg and the AMA, this demonstrates how editors' interests can conflict with those of their journals' owners, and the implications this can have on editorial independence. In 2016, the CMA fired its new editor, John Fletcher, while simultaneously disbanding the organisation's instrument that supposedly protected editorial independence, its Journal Oversight Committee (JOC) (see Chapter Seven, Section 7.2.3 for more on this). The reasons for the letting go of Fletcher were not made clear, other than the CMA stating that it wanted to 'recast CMAJ as a world-class leading journal' (CMA, 2016a). However, the fact that it coincided with the dissolution of the JOC resulted in concerns that it was to do with a desire to bypass editorial independence and make the journal more profitable (WAME, 2016b, Smith, 2016). The current dominating system of journal rating, the Impact Factor (IF), can also influence which articles editors may accept (Editors, 2006), with it being likely that those which are expected to be highly cited stand greater chance of being published (Marcovitch, 2010). Evidence shows that industry-sponsored trials are cited more than those with other sources of funding (Conen et al., 2008, Kulkarni et al., 2007, Lundh et al., 2010): Lundh et al. found that industry-supported trials published in 2005-06 in *Annals of Internal Medicine*, *Archives of Internal Medicine* and *The Lancet* were cited more than twice as many times as non-industry trials, and one-and-a-half more times in the *BMJ*, *JAMA* and *NEJM*.

Journal editors also may face personal financial COIs, such as if they hold a personal financial stake in a commercial company. For example, in 1992, the *Journal of Clinical Epidemiology* published letters criticising research published in *Circulation* on deaths caused by second-hand tobacco smoke. The editor of *Circulation*, Alvan Feinstein, was a long-time recipient of undisclosed tobacco

industry funds. A more recent example relating to the pharmaceutical industry is that of Thomas Zdeblick. Zdeblick, former editor in chief (EIC) of the *Journal of Spinal Disorders & Techniques*, was found to have received more than US\$20 million in patent royalties and US\$2 million in consulting fees from Medtronic for spinal implants that the company sold while he was in post, without stating this relationship to his readers (Lenzer, 2010); the journal's publisher Wolters Kluwer Health & Pharma Solutions defended the relationship (Lenzer, 2010, Samson, 2011). Yet despite the fact that editors can face COIs that could affect their journals, a study in 2004 of 30 journals by Haivas et al. (2004) found that only nine have an explicit policy on editors' financial COIs, with only the *BMJ* publicly declaring them on its website. Only 23 per cent declare their non-financial COIs of their editors (Ibid). There are also few mechanisms in place to ensure the declarations are updated, and it is not made clear to readers how the policies are implemented or financial COIs defined (Ibid).

#### *2.3.1.3 Reviewers*

Reviewers of articles also potentially have COIs that could affect their commentaries. As with other actors, these can be financial (such as shares in a company whose drug is under discussion), or other (such as academic competition or personal friendships with the authors of the article, religious beliefs, or personal beliefs in the strengths or weaknesses of particular treatments) (Marcovitch et al., 2010, Young, 2009). An early study by Mahoney (1977) found that reviewers experienced confirmatory bias, whereby they were strongly biased against manuscripts that conflicted with their own theoretical perspectives. However, as Young (2009) there is limited research into sources of reviewers' bias and how these could best be managed.

#### **2.3.2 Bias in clinical research**

Tereskerz et al. (2009) surveyed U.S. medical schools to investigate the effects of financial relationships between faculty and manufacturing sector companies on clinical research. Significant numbers of respondents to their study based in

units with industry support noted compromises to: research initiatives (35%), publication (28%), interpretation of data (25%), and overall scientific advancement (20%). While this thesis focuses upon COIs in medical journal publications, those publications depend upon the work that they contain, and therefore the way in which conflicts can bias the research studies must also be considered (Bero and Rennie, 1996). The following section thus looks at the ways in which clinical research can be biased, before progressing, in Section 2.4.3, to discuss further the ways in which actors' COIs have been depicted as causing the content of journals to be biased.

The ways in which studies are framed – their design – is one way in which research, conducted by conflicted parties, can impact on the literature, for example through the clinical relevance of the research questions and the appropriateness of the control intervention (Lo and Field, 2009, Sismondo, 2008b). Bero and Rennie argue that an ideal clinical drug study 'would assess the effectiveness, toxicity, convenience, and cost of a new drug compared with available alternatives, would be designed to reduce systematic bias; and would draw conclusions that flow directly from the results' (1996, p. 211). However, as discussed above, this is not always the case, with factors such as industry funding leading to inappropriate research practices. There are various ways in which study designs can be adjusted to achieve desired results. For example, asking research questions that are too narrow may provide incomplete and misleading information, and thus not adequately inform a prescriber which drug to offer their patient (Bero and Rennie, 1996). While it is not only researchers sponsored by industry who may allow bias to frame their studies, several systematic reviews and other studies have provided substantial evidence that clinical trials with ties to the pharmaceutical industry are more likely to have results that favour their sponsor than those without such ties (Lo and Field, 2009, Yank et al., 2007). The pharmaceutical industry is not alone in engaging in such practices: tobacco companies have also been found to control research through the questions asked, and the design and conduct of the research (Bero, 2005, Barnes and Bero, 1996). Critics have argued that this could be because



industry studies are less rigorously designed, or designed in such a way that bias the findings in their favour. This can be done, for example, through accentuating positive outcomes while de-emphasising negative ones; presenting statistically insignificant results as clinically important; and switching primary and secondary endpoints around (Boutron et al., 2010). Methodologies can also be adjusted to benefit the drug sponsor in various ways. Using unrepresentative study patients is one, whereby drugs are tested in healthier populations (for example, with less serious versions of the disease) than those for whom it is targeted. This means that the drug may likely be found to be more efficacious than is actually the case. Another way to make a new drug appear more effective is by testing it against an insufficient dosage of a competing drug (Rochon et al., 1998, Bodenheimer, 2000). Rochon et al. (1994b) found that, in trials for nonsteroidal anti-inflammatory (NSAIDs) drugs, only 2.1 per cent of the subjects were 65 years or older, despite the fact that these drugs are more commonly used, and have more side effects, in elderly populations. They also found that in 48.2 per cent of the trials, a higher dose of manufacturer-associated drug was found to be given than that of the comparison drug. Not truly blinding study subjects and researchers to treatment allows bias towards the therapy being tested: in a study on NSAID trials, Gøtzsche (1989a) found that eight per cent of trials that claimed to be double-blind were probably not truly so, while Colditz et al. (1989) found that only 27 per cent of 128 medical studies were double blinded. Biased clinical trials may also use many surrogate end points that may not relate to more important clinical end points, and publish the results of those that favour their drug (Psaty et al., 1999, Bero and Rennie, 1996, Temple, 1999).

### **2.3.3 Publication bias**

The focus of this thesis is on peer-reviewed medical/health journals. While conflicts can cause studies (which may go on to be published) to be biased, they can also have an effect on publishing decisions. Publishing decisions based on a study's findings is known as 'publication bias' (Dickersin, 1990). It results from the COIs of those actors involved in medical publishing. There are various

practices that constitute publication bias; for more detail see: Begg and Berlin (1988), Bero and Rennie (1996), Edmond (2008), Martinson et al. (2005), Melander et al. (2003), Roberts (2009), Smith (2005). These practices are seen by some as having the potential to distort the literature (Ross et al., 2012): through multiple publication of positive studies, and the concealment of negative ones, any further systematic reviews or meta-analyses will be skewed. This could ultimately have a detrimental effect on decisions made by policy-makers and doctors, could be costly for health services and could potentially harm patients (Turner et al., 2008).

Practices associated with publication bias include the suppression of negative results. A systematic review by Lexchin et al. (2003) found that pharmaceutical industry-sponsored research is less likely to be published than studies funded by other sources, indicating the suppression of negative studies; stipulations in some contracts with researchers allow pharmaceutical companies to refuse to have results published (Schott et al., 2010). For example, Turner et al. (2008) compared published trial articles with trial reports submitted to the FDA for review, and found that 31 per cent of antidepressant trials were not published. Ross et al. (2009) found that less than half of the trials registered in ClinicalTrials.gov (the publicly accessible, Internet-based registry of clinical trials managed by the National Library of Medicine in the U.S.) had been published; the trials with the lowest rate of publication were those sponsored by industry. The tobacco industry has also suppressed research with results that are unfavourable to it (Kleiner, 1994).

Another practice associated with publication bias is that of multiple publication (publishing the same study in more than one article). Lexchin et al. (2003) found that studies sponsored by commercial companies were more likely to have positive results favouring them than companies with other types of funders: Rochon et al.'s review of 61 published industry-sponsored randomised controlled trials involving NSAIDs found that none had negative findings (Rochon et al., 1994b). Melander et al. (2003) compared 42 placebo-controlled

studies of five selective serotonin reuptake inhibitors submitted to the Swedish drug regulatory authority as a basis for marketing approval for treating major depression with published studies, and found that 21 studies contributed to at least two publications each, while three studies contributed to five publications. Studies by Gøtzsche (1989b) and Johansen and Gøtzsche (1999) found that industry sponsorship is associated with multiple publication of positive results. Industry-sponsored research also does tend to report pro-industry conclusions, even if the results do not support them (Bekelman et al., 2003, Bero et al., 2007).

Practices relating to publication bias have been linked particularly to industry-funded trials (Lexchin et al., 2003, Melander et al., 2003). However, while it is less common, researchers who are not commercially funded have also been found to employ tactics related to publication bias (Hirsch, 2009), resulting from their own non-financial interests. Smith (2010) and Dreger (2015) have discussed how funding from the third-sector and government can cause academics to experience conflicts in the types of research they pursue. Research studies on breastfeeding, with no industry involvement, found that in some cases positive results were more likely to be published than other data, suggesting that other motivations were at play that were not related to commercial funding (Horta et al., 2007). Stell (2010) alleged that the authors of a study examining treatment for mild gestational diabetes during pregnancy (Landon et al., 2009) put the protocol ahead of subject safety, which resulted in a trial design that exposed control subjects to excessive risk of harm; because they had no financial COIs, the authors were able to declare on the paper that they had no conflicts, yet as discussed by Levinsky (2002), their desire for career advancement, may have conflicted with their responsibility to protect their study participants. Work in the sociology of science has looked at how government and third-sector funding can lead to conflicts, with academics facing pressure to produce particular types of research. Gieyrn has discussed how other intellectual activities, such as political ideologies, can conflict with the scientific process (1983). Academic scientists also face professional pressures to get papers published in journals and this may conflict with their desire to ensure that they only publish good

quality, sound research. Saver (2012) argues that the evidence base regarding the prevalence and influence of non-financial COIs is limited, but cautions that it is premature to dismiss non-financial COIs as posing considerably less risk than financial ones that do not require regulation.

It has been argued by some that journal editors may themselves be more receptive to publishing positive trials than negative ones, because they are more likely to be read and cited, and thus result in orders of reprints and an improved IF (Lundh et al., 2010, Smith and Roberts, 2006). However, a study by Dickersin et al. (1987) similarly found that non-publication of studies was primarily a result of failure to write up and submit the trial results rather than rejection of submitted manuscripts. Bero and Rennie (1996) found that in areas of research other than drug studies, approximately 50 per cent of articles published were of negative studies, and thus suggested that the bias lies with those submitting the drug studies, rather than the editors. A more recent study by Rising et al. (2008) also found that trials were not published because authors did not submit them to journals, rather than the journals rejecting them.

Another form of publication bias involves the use of professional medical writers to develop articles, without declaring their involvement: this constitutes a practice known as 'ghost-writing' (Moffatt and Elliott, 2007); Ross et al. define ghost-writing as 'the failure to designate an individual (as an author) who has made a substantial contribution to the research or writing of a manuscript' (2008, p. 1800). Evidence shows that both the pharmaceutical and tobacco industries have employed undisclosed professional writers to develop articles (e.g. Ross et al., 2008, Grassley, 2010, McHenry and Jureidini, 2008, Landman and Glantz, 2009, Grüning et al., 2006, Muggli et al., 2003, Hong and Bero, 2002, Rampton and Stauber, 2002). Such articles are often 'authored' by 'Key Opinion Leaders': those who are considered influential leaders in their field, and may include physicians, scientists or academics (Rampton and Stauber, 2002, Elliott, 2004, Liesegang, 2008, Matheson, 2008, Moynihan, 2008, Drope and Chapman, 2001, Applbaum, 2010, Applbaum, 2009, Muggli et al., 2003, Muggli et al., 2001,

Grüning et al., 2006, McHenry, 2005, McHenry and Jureidini, 2008). These 'guest' or 'honorary' authors, who seemingly have no financial connection to the drug (Moffatt and Elliott, 2007) typically receive payment (Anekwe, 2009). Their involvement gives the research the appearance of credibility and objectivity, yet the literature published under their names strengthens the industry's position and may undermine opposing research (Liesegang, 2008, Matheson, 2008, Moynihan, 2008). Ghost-written articles usually form part of a corporate promotional strategy of a product, emphasising its importance and downplaying any negative effects (Egilman and Druar, 2011, Moffatt and Elliott, 2007). There are arguably degrees of ghost-writing (Ngai et al., 2005), with the most extreme being described above. Less extreme, but still problematic, examples include allowing a study's commercial sponsor to collect and hold the trial data; solely using a sponsor's statistician; and permitting a sponsor to draft a manuscript or control its content and conclusions (Moffatt and Elliott, 2007). The use of company statisticians to perform analyses has been included in studies on ghost authorship, with it being found that they are frequently not acknowledged (Gøtzsche et al., 2007).

## **2.4 Hiding industry support**

A number of researchers have examined the marketing documents of both pharmaceutical and tobacco companies that have been disclosed in lawsuits to explore the ways in which these industries have used journal articles to promote their products. Such lawsuits are infrequent, and only occur some time after the drug trials have taken place and the articles written; the result of this is that the evidence of these practices is relatively dated. This research is also limited in that it is restricted to the documents that have been made available in these lawsuits (Davis, 2008). However, they do offer some insights into the practices employed, and the following section looks at the studies conducted on these internal industry documents, providing case studies of the use of the techniques described in Section 2.5.

There have been concerns over the practice of ghost-writing in medical/health journal publishing since the 1990s, before the release of the industry documents. In 1998, Flanagin et al. conducted the first study into the practice, attempting to establish its prevalence across the board. The authors used three high-circulation journals with the highest IF (*Annals of Internal Medicine*, *JAMA*, and the *New England Journal of Medicine*), together with three low-circulation journals which had been known to publish supplements (*American Journal of Cardiology*, *American Journal of Medicine*, and *American Journal of Obstetrics and Gynecology*). They found that out of 809 articles surveyed (original research reports, review articles and editorials), 156 had evidence of guest authors; 93 demonstrated evidence of the involvement of ghost authors; and 13 articles had evidence of both. They did not find a significant difference on the use of guest authors between the high- and low-circulation journals; in terms of ghost authors, the low-circulation ones were more likely to use ghost authors for review articles and less for research ones. However, because of the relatively low response rate, as well as the dependence on the honesty of participants, it has been suggested that the prevalence across the board is probably higher than this research demonstrates (Gøtzsche et al., 2007).

After a number of lawsuits against various pharmaceutical and tobacco companies, further detailed investigations into the practices of such organisations have since been undertaken, using the company documents released in the litigation (see UCSF, n.d.). In particular, these help to illustrate how ghost writers have been utilised in order to produce articles for publication in medical/health journals that portray drugs in a positive light, while hiding the companies' involvement (see Steinman et al., 2006, Ross et al., 2008, Elliott, 2004, Fugh-Berman, 2010, Healy and Cattell, 2003, McHenry, 2005, McHenry, 2010, McHenry and Jureidini, 2008, Jureidini et al., 2008).

Amongst these, several highlight how particular journals published ghost-written articles. Elliott (2004) examined documents on Wyeth's marketing of its anti-obesity drug, dexfenfluramine (Phen-Fe), which was

approved by the FDA in 1996, despite existing concerns that it was linked to valvular heart disease. The drug was withdrawn from the market in 1997 and Wyeth has acknowledged that at least 45,000 users became ill because it, and potentially many hundreds died. According to the documents, Wyeth employed a medical writing company, Excerpta Medica, to ghost-write articles which portrayed the drug positively and downplayed the risks of side effects; academics were paid to edit drafts and put their names to articles. Excerpta Medica planned to submit the majority of the articles to journals owned by their parent company, Elsevier. Ultimately, only two were published before the drug was withdrawn, both in Elsevier journals – *Clinical Therapeutics* and *American Journal of Medicine*. In neither article was the fact that Excerpta Medica had paid the named authors disclosed (Elliott, 2004).

Industry documents have also demonstrated the ways in which SmithKline Beecham<sup>3</sup> (SKB) used medical journal articles to promote its SSRI drug Paroxetine (Paxil/Seroxat). The marketing of Paxil for unapproved uses, including via publications in medical journals, resulted in the company being fined US\$3 billion in July 2012 for research fraud, of which this was a part. Public relations firm Ruder Finn was hired by SKB to work with its marketing department in response to Eli Lilly's attempts to discredit Paxil, and industry documents portray how Ruder Finn prepared papers for medical journals which included ghost-written letters to *The Journal of Clinical Psychiatry* (Jureidini et al., 2008, McHenry, 2005, McHenry and Jureidini, 2008, McHenry, 2010). Documents show SKB's concerns over references included in the letters, fearing that they may be too similar and thus raise suspicions over their authenticity (2010, McHenry, 2005). McHenry's analysis of a published letter demonstrates that it is an expanded version of a draft prepared by Ruder Finn, that it defends Paroxetine, and that it does not acknowledge any involvement of SKB or Ruder Finn (McHenry, 2005). This letter was also referred to in company marketing

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<sup>3</sup> SmithKlineBeecham Plc merged with Glaxo Wellcome Plc in 2000 and became GlaxoSmithKline.

documents before it was published. This demonstrates awareness within SKB of its existence prior to its publication, and further highlights that it was not an independent communication (McHenry, 2005). Industry documents also show that an important article about a key trial on the use of Paroxetine in adolescent depression, Study 329, was ghost-written and that it misrepresented data. This article appeared in *The Journal of the American Academy of Child and Adolescent Psychiatry* and gave the impression that the data proved the trial was a success. It had in fact failed for both efficacy and safety (McHenry, 2005).

There is less discussion on the practice of ghost-writing in relation to the tobacco industry. However, internal industry documents do show similarities between it and the pharmaceutical industry's use of publications and ghost writers (Rampton and Stauber, 2002). Rather than using medical writing companies, law firms were employed to liaise between the tobacco companies and scientists (Drope and Chapman, 2001, Muggli et al., 2003) and organise publications (Hong and Bero, 2002, Rampton and Stauber, 2002). Hong and Bero have written about the tobacco industry's campaign regarding Environmental Tobacco Smoke, and they refer to its use of ghost-written publications as part of the industry's attempt to underplay the risks associated with passive smoking and to discredit opposing studies (Hong and Bero, 2002). Industry scientists and consultants were employed to write articles, yet in the final publications, not all of those who qualified for authorship were named on the by-line. A study by Fields and Chapman (2003) documents the ways in which the tobacco firm Philip Morris targeted a prominent U.S. scientist (Ernst Wynder) who researched smoking and disease. Initially considered a problem by the industry due to his research on the harms caused by smoking, PM provided Wynder with research funding, which resulted in his producing work favourable to the industry. This included being a guest author on an article that appeared in the *Journal of the National Cancer Institute* that emphasised the role diet played in lung cancer. The paper was ghost-authored by a PM employee, Jet Lincoln, yet the published article bore no mention of his name, or that of PM (Fields and Chapman, 2003).



As well as the use of ghost writers, which hides the involvement of commercial companies from readers, it has also been found that researchers who are sponsored by industry have, at times, failed to acknowledge on research published under their name the source of that funding. This thus gives the articles the deceptive appearance of being free of involvement of the manufactures of the product under discussion. For example, in 1988, Philip Morris hired, via lawfirm Covington and Burling, three scientists who already worked for the company as Nordic Environmental Tobacco Smoke (ETS) consultants: toxicologist Torbjorn Malmfors, statistician Daniel Thorburn and occupation hygienist Arne Westlin (Nielsen and Glantz, 2004). These scientists were paid by the CIAR to conduct a study, alongside industry scientists, on in-air flight quality on the Scandinavian airline SAS. Philip Morris designed the study, and while it employed an outside laboratory to collect the data, it oversaw the study closely and conducted the analysis itself. Philip Morris closely controlled the report from the laboratory, as well as the resulting paper by Malmfors, Thorburn and Westlin. Drafts of this paper were circulated to senior industry scientists, and industry scientists and lawyers were involved in revising it. The final article, published in *Environmental Technology Letters* (Malmfors et al., 1989), presented data in a misleading light. There was a simple acknowledgement that 'The authors have served as consultants to CIAR', which did not adequately describe the full involvement of the industry and the funding it provided as described above (Ibid, p. 627). Tobacco industry documents also show how a coalition of tobacco companies (the Commodity Industry Coalition) hired consulting firm Sciences International to produce favourable research that supported the existing standards on the pesticide phosphine (McDaniel et al., 2005). Sciences International was headed by Elizabeth Anderson, who was also editor of the journal *Risk Analysis*. The consultancy took further funding from the coalition to turn their research into a peer-reviewed journal article which was published in *Risk Analysis* (Ibid), acknowledging only that 'This work was supported by the Phosphine/Metal Phosphide Coalition, consisting of the producers and users of phosphine and metal phosphides for the control of insects in stored commodities' (Pepelko et al., 2004).

Companies have also been found to have removed researchers' names from articles, when the latter have expressed concerns over the misrepresentation of their data. For example, the principal investigator of a study in 1991/1992 examining the effects of Environmental Tobacco Smoke was E. Yano. He provided an employee of Covington and Burling, Dr Christopher Proctor (later head of British American Tobacco's Science and Regulation), with the data, from which Proctor developed a draft. When Proctor shared these drafts with Yano, there was no mention of Proctor on them. Yano disagreed with the conclusions in the drafts, which overstated his conclusions, and expressed discomfort to Proctor with the way in which the data had been construed. He later discovered the paper was published, without his consent and with the results he disagreed with, in a journal *International Archives of Occupational and Environmental Health* under the name of a consultant to the tobacco industry, Peter Lee (Yano, 2005, Chapman, 2005). He further realised that earlier drafts (including ones he had never seen) bore his and a co-author's (Kagawa) name, although they had not written any of it.

## **2.5 Managing conflicts of interest: disclosure**

### ***2.5.1 The strengths and weaknesses of disclosure***

As discussed so far in this chapter, COIs and resulting bias can have a potential impact on research and the resulting literature. Effective systems are therefore required to ensure that they are properly managed. This thesis is most concerned with how COIs are managed in peer-reviewed medical/health journal publications. The strategy most commonly used in a range of fields such as business, government, media, academia and medicine to manage COIs is voluntary disclosure of any potential conflicts to recipients of the information (Loewenstein et al., 2011, Cain et al., 2005b). This is also the primary mechanism used in medical journal publishing, which will be discussed in more detail in Section 2.5.2. (Resnik, 1998, Sharpe, 2002). There are strengths to this process, yet research has demonstrated that it also entails various weaknesses (see

Pronin et al., 2004, Cain and Detsky, 2008, Cain et al., 2005b, Cain et al., 2011, Cain et al., 2005a, Loewenstein et al., 2011, Loewenstein et al., 2012, Dana and Loewenstein, 2003, Sah et al., 2013).

Church and Kuang (2009) suggest that disclosure is appealing to regulators as it is a low-cost solution that requires no considerable change: a 2005 editorial by the then editors of *JAMA* argued that the process offers transparency and arguably improves honesty and trustworthiness (Fontanarosa et al., 2005). Sah and Loewenstein (2014) argue that its strength lies in its potential influence on the behaviour of those who are disclosing. They suggest that those from whom disclosure is required will theoretically be more willing to disclose their interests, rather than hide them and risk their discovery, which would result in damage to their reputation. Koch and Schmidt (2010) discuss the 'sender-receiver' model, according to which, advisors may be less likely to give biased advice when they have disclosed, as the advisees will be aware of the misalignment of incentives and therefore be less trusting of them. Knowing that their peers may examine their work more carefully in the light of any disclosures, the process may therefore cause advisors to be more balanced in the advice they give. Disclosure is based on the premise that a conflict cannot be resolved; thus transparency informs the recipient of the disclosure of the conflict's existence (Kassirer, 2009b) and arguably allows them to interpret the information they are given more appropriately and in its correct context, consequently helping to maintain trust in the medical research (Fontanarosa et al., 2005).

However, critics argue that, while disclosure is an important element in the management of COIs, it is not in itself sufficient. As discussed in Section 2.2 of this chapter, actors may have a 'blind spot' where their own conflicts are concerned (Pronin et al., 2004), and thus not be aware of their own biases (Cain and Detsky, 2008, Dana and Loewenstein, 2003). Cain et al.'s (2005b) study on the effects of disclosure discussed two further possible unintended but negative consequences that can arise as a result of the practice: 'moral licensing' and 'strategic exaggeration'. Having dispensed of their ethical duty by disclosing

their COIs, the 'moral licensing effect' sees people unconsciously feel that it is acceptable for them to act in a more self-serving way than they would have done otherwise: it may strengthen their conflict (Kassirer, 2009a). 'Strategic exaggeration' assumes that people may embellish and overstate their advice due to concerns that it will be discounted (Jamal, 2012, Loewenstein et al., 2012, Cain et al., 2005b, Cain and Detsky, 2008). Thus, Cain and Detsky argue that, rather than having a positive influence, disclosure may perversely make a situation worse (2008).

How disclosure influences recipients' interpretation is also debatable (Kassirer, 2009a, Ben-Shahar and Schneider, 2011, Loewenstein et al., 2012, Sah et al., 2013, Cain et al., 2005b, Cain et al., 2005a). Recipients of disclosures are likely to have difficulty in judging just how much of an effect a conflict will have had on the information that they receive (Elliott, 2008, Kassirer, 2009b). Research on the effects of disclosure on recipients of information gives mixed messages: some demonstrates that physicians simply ignore disclosure statements (Silverman et al., 2010), while other studies show that disclosure of substantial conflicts can cause clinicians to discount trial results (Chaudhry et al., 2002, Lacasse and Leo, 2011). Camerer et al. (1989) found that people can in fact be influenced by information, even when it might be in their interest to ignore it: this is known as the 'curse of knowledge'. They 'anchor' on to it (Tversky and Kahneman, 1974) and are then unable to properly adjust their interpretations sufficiently in accordance with the potential conflict, even when they know that it may have led to biased information (Loewenstein et al., 2011). Indeed, some research has found that disclosure can actually lead to an increase in trust, as it is interpreted as a sign of honesty (Cain et al., 2011).

Bero (1999) argues that disclosure in medical journal publishing, while useful, is not sufficient: it does not necessarily eliminate the influence of industry funding, and it is difficult to enforce. Some argue that the only effective way to prevent COIs leading to biased information is through the avoidance of them altogether (e.g. Kassirer, 2009b). Even with disclosure, COIs (and any resulting

potential bias) continue to exist, and thus COIs should instead be avoided altogether (Resnik, 1998, Kassirer, 2009a, Glaser and Bero, 2005).

### ***2.5.2 Studies on conflicts of interest policies in medical/health journals***

The *NEJM* was the first medical journal to produce a COI policy in 1984, in response to growing concerns regarding COIs in medical journals. This required the disclosure of research funding (Rothman, 1991, Kassirer and Angell, 1993, Relman, 1984). In 1997, the International Committee of Medical Journal Editor's (ICMJE) revised its *Uniform Requirements for Manuscripts Submitted to Biomedical Journals Studies*, stating that authors should acknowledge financial and material support, and disclose relationships that may pose a COI (ICMJE, 1997). The following section looks at 11 studies that have been conducted on COIs and the disclosure policies of journals (Krimsky and Rothenberg, 2001, Krimsky and Sweet, 2009, Cooper et al., 2006, Ancker and Flanagin, 2007, Blum et al., 2008, Weinfurt et al., 2008, Rowan-Legg et al., 2009, Bosch et al., 2013, Kesselheim et al., 2012, Gross et al., 2003, Blum et al., 2009).

The studies generally demonstrate an increase in the existence of journal disclosure policies over the time period in which they were conducted. For example, Rowan-Legg et al.'s (2009) study compared the ethical guidelines of 103 English language biomedical journals in 1995 and 2005, selected from the 2005 edition of the *Abridged Index Medicus* (their Impact Factor (IF) is not made clear in the article). The authors found that, over that period, the proportion of journals requiring disclosure of COIs increased from 75 to 94 per cent. A study conducted by Krimsky and Sweet (2009), which examined the COI policies of 47 toxicology and 180 medical journals, found that 87 per cent of the toxicology and 84 per cent of the medical journals had COI policies. While the selection criteria differs from a study by Krimsky and Rothenberg in 2001 (which looked at 1,396 science and biomedical journals with a high IF), it does indicate an upward trend in the inclusion of COI policies; Krimsky and Rothenberg found that in 1997, roughly only 16 per cent of the journals had COI policies (Krimsky and

Rothenberg, 2001).

Ancker and Flanagin (2007) found that higher IF journals are more likely to provide published COI policies than lower IF ones, with the frequency of policies dropping linearly with IF ranking; in 2008 Blum et al. found that most journals with a high IF had disclosure policies (Blum et al., 2008). Similarly, Weinfurt et al. (2008) found that articles in higher IF journals were more likely to include disclosure statements for all authors on articles, as were journals that endorsed the ICMJE's guidelines. In a cross-sectional study of 399 journals in 27 biomedical categories of the Journal Citation Index (JCI), on their publicly available information regarding COIs and disclosure, Bosch et al. (2013) also found that journals with a higher IF (in the first decile of the JCI) were more likely to have disclosure policies on authors' financial and non-financial, and editors' (unspecified) COIs than those with a lower IF (in the second decile). Further findings of this study included: clinical journals scored better than basic journals for all disclosure policies (on authors' financial and non-financial, and editors' (unspecified) COIs), and no difference was found between Open Access (OA) and non-OA journals for any type of disclosure.

While the number of journals with COI policies appears to be increasing, studies have found that their content and requirements differ. Blum et al. (2008) found a great deal of variability across the 67 peer-reviewed medical journals they studied with regards to their COI policies, the types of disclosure required and their communication of this information to authors. They argued that this inconsistency could ultimately undermine the goals of the policies. They found that 64 per cent required all authors of a manuscript to sign a statement disclosing any possible COIs; 61 per cent asked for disclosure of funding support; 91 per cent asked for disclosure of possible COIs in their Instructions for Authors; and 67 per cent defined or gave examples of possible COIs. A more comprehensive, in-depth study by the same authors (Blum et al., 2009) looked at 256 journals (the top 10 per cent of 2117 medical journals from 35 subject categories as measured by IF) to determine the prevalence and variability of COI

disclosure requirements and definitions; the results of this larger study found again that there were variations in the policies across journals, which could lead to inconsistencies in what is declared: 89 per cent of the journals had COI policies; 54 per cent required authors to sign a COI statement; and 77 per cent provided definitions of COIs (which were mostly limited to financial interests). Ancker and Flanagin (2007) found many journal policies were not readily available to submitting authors, and lacked clear definitions or information on how disclosures would be managed during the peer-review process and publication. There was also little consensus amongst journals on definitions of COIs, how they should be managed, what were relevant time frames, and what types of COIs were most problematic. Ancker and Flanagin (2007) found that 54 per cent of their sample journals did not provide definitions of COI. Rowan-Legg et al. (2009) found that in the journals from their 2005 sample, 24 per cent were vague in describing what constituted a COI beyond funding. Only 42 of the 103 journals had comprehensive instructions regarding COI disclosure (this was an increase from only two in 1995), while 10 were vague. Krinsky and Sweet (2009) found that in over 75 per cent of their sample, the level of specificity (stipulating monetary thresholds, time considerations, non-financial competing interests and sanctions for violations of the policy) was minimal or almost non-existent, and the comprehensiveness of more than 80 per cent was minimal to narrow, thus allowing authors a great deal of discretion in reporting their COIs. Rowan-Legg et al. (2009) found that 41 per cent of journals in their sample had comprehensive requirements. However, they also found that six per cent addressed only funding source, 10 per cent contained only vague statements on disclosure, and 14 per cent were both vague and only discussed funding (Rowan-Legg et al., 2009).

The actual impact of these disclosure policies has been contested. While there does seem to be an increase in compliance with disclosure policies – for example, in Krinsky and Sweet's study (2009), 41 per cent of the authors of all the articles in those medical journals with COI policies disclosed conflicts, as opposed to Krinsky and Rothenberg's earlier study which found that less than

one per cent of articles contained author disclosures in journals with disclosure policies (Krimsky and Rothenberg, 2001) – studies still indicate that a lot of COIs remain undeclared. Kesselheim et al. (2012) analysed industry documents that had been released in litigation between 1996 and 2010 to identify physicians and scientists who had been accused of having financial relationships with defendant manufacturers. They then searched Medline for articles authored by these researchers in the following three years and found that, out of the 39 authors identified as conflicted, who had published a total of 404 relevant articles, only 15 per cent provided an adequate disclosure statement, as per the ICMJE's requirements for disclosure. The study does not make it clear whether the journals they published in required author COI disclosure, but it does perhaps demonstrate reticence amongst some conflicted authors in disclosing relevant information. Gross et al. (2003) identified 268 randomised controlled trials published in high IF journals, and examined them to see how closely the journals adhered to the ICMJE's disclosure requirements (ICMJE, 1997). While 100 disclosed support from industry, 69 of these included the nature of the relationship between the authors and the study sponsor, while only eight reported the role of the study sponsor in the methods section (as recommended by the ICMJE). Six of these described the sponsor's role, but with vague wording. They concluded, thus, that while industry involvement was substantial in these trials, the true extent and nature of it was difficult to assess because of variable adherence to the disclosure guidelines.

Weinfurt et al. (2008) carried out a study of 746 articles with 2985 authors published in 135 cardiovascular journals, examining whether their COIs were consistently reported. They found that 83 per cent of the articles did not contain disclosure statements for any author, 72 per cent did not identify any funding source and only six per cent of authors had an article with a disclosure statement. The authors also compared articles written by the same authors, and found that in 34 per cent of cases, disclosure statements were made on some articles, but not on others by the same author. This could be because the interests which conflict on certain studies do not on others; because of



inconsistency in what journals require to be disclosed; or because of deliberate concealment of interests on the part of authors in some publications and not others (though this latter possibility is perhaps less likely if they have declared them on some articles).

Cooper et al. (2006) identified various other issues with journal disclosure policies. In the case of author disclosures, they are not required to provide it on all types of submissions: almost a quarter of journals require it only on original research articles, but not on narrative reviews or editorials, despite the fact that these are opinion pieces without methodologies. The disclosure information is often not published (57 per cent in the case of authors; three per cent for peer reviewers; and 12 per cent for editors). And only 8.8 per cent of the 91 journals surveyed, from among the highest IF journals, had a formal policy to verify the accuracy of disclosure by all parties; the other journals simply rely on author honesty

The majority of journal disclosure policies are aimed at authors. Cooper et al. (2006) conducted a cross-sectional survey of 91 journals from a range of medical fields (selecting those with the top IF in their field), sent to editors, in order to quantitatively assess journal policies for the COIs of authors, editors and peer reviewers. They found that more journals have COI policies for authors (77 per cent) than peer reviewers (46 per cent) or editors (40 per cent). All of the sample journals in Ancker and Flanagan's (2007) study had policies directed at authors (72 per cent), followed by policies directed at peer reviewers (59 per cent) and editors (56 per cent). Bosch et al. (2013) conducted a cross-sectional study of 399 journals in 27 biomedical categories of the Journal Citation Index (JCI), on their publicly available information regarding COIs and disclosure. They found that authors were required to provide financial COI disclosures by 89.7 per cent, and non-financial disclosures by 70.2 per cent, of the journals. However, only 38.8 per cent of journals required disclosures from editors. In the most recent study included in this section, Shawwa et al. (2016) looked at the 117 peer-reviewed English language clinical journals in the *Abridged Index*

*Medicus*. They found that all but one had a COI policy, and required disclosure of financial COIs. However, they found that only 57 per cent required disclosure of at least one form of non-financial COI, disclosure of financial COI of family members and institutions of the authors, and effect of disclosed COI or non-disclosure of COI on editorial policies.

## **2.6 Concluding summary**

The literature on COIs and bias from both the social science and medical/health research fields has been brought together in this chapter. It began, in Section 2.2, by providing an overview of the existing theoretical debates surrounding the conceptualisation of COIs. It then continued by looking, in Section 2.3, in more detail at how the literature suggests that COIs can affect medical journal publications. While they may have some positive outcomes, the increase in relationships between the pharmaceutical industry and academic researchers has led to greater risk of potential COIs. Studies have been conducted on internal industry documents which demonstrate the ways in which the pharmaceutical and tobacco industries have used journal publications to promote their products, and these are discussed in Section 2.4. In Section 2.5.1, the chapter returned to the social science literature, examining studies on COI management, in particular the policy of voluntary disclosure, considering strengths and weaknesses. Given the potential for COIs to occur from these relationships, effective management is necessary, and various studies have been conducted on the COI policies of journals. In Section 2.5.2, these were critically examined.

This chapter demonstrates that, while there is in general agreement amongst scholars on what broadly constitutes a COI, namely with it being ‘a set of conditions in which professional judgment concerning a primary interest ... tends to be unduly influenced by a secondary influence’ (Thompson, 1993, p. 573), there appears to be a lack of consensus regarding details such as how ‘interest’ should be defined. The literature tends to focus on financial COIs, demonstrating how these are considered to be the main types that are of

concern. The studies examined in Section 2.5.2 indicate that there is overall more focus given to financial interests in journal policies and guidance. However, as shown in this chapter, other, non-financial types of interests may also arguably result in conflicts. Understandings of what can constitute COIs in medical/health journal publishing will be explored in greater depth in this research, and the implications of these examined.

The literature discussed in this chapter shows that attention is particularly given to research funding from private companies. In particular, as this chapter has shown, the involvement of both the pharmaceutical and tobacco industries in funding research, and their influence over resulting publications, has been particularly debated and contested. As such, this thesis focuses on these two industries when examining the COIs that can result from sponsorship of research by private companies.

It has been shown in this chapter that disclosure is the main method currently employed to manage COIs in most fields, including within medical journal publishing. Section 2.5.1 looked at research that has been conducted into the strengths and weaknesses of this practice. While some studies show that in particular circumstances it can be effective, multiple concerns have been raised, including unintended consequences such as ‘moral licensing’ and ‘strategic exaggeration’ (Cain et al., 2005b), which result in the opposite of the intended consequences, demonstrating that on its own, it is not a reliable solution. This is born out in Section 2.5.2, which examines existing studies that have been conducted on disclosure policies in medical journals. These quantitative studies assess a variety of aspects of journal disclosure, and use a mix of selection criteria, so it is hard to draw definitive conclusions on what they show; however, certain themes emerge from which inferences regarding the process can be drawn. They show that, while there has been an increase in the existence of journal disclosure policies over the time period in which the studies were conducted (from 1997 until 2016), and that there are some aspects of them which are helpful in the management of COIs, such policies are far from

providing an entirely effective solution to COIs in medical journal publishing. This thesis will explore in greater depth this reliance upon disclosure, and whether it can be improved.

The focus of the studies discussed in Section 2.5.2 is on authors, with limited attention given to other actor groups, such as editors, reviewers and contributors. Yet, as shown in Sections 2.3.1.2 and 2.3.1.3, editors, journal owners and reviewers can all potentially have interests that could result in conflicts affecting journals. This perhaps reflects a generally narrow focus within medical journal publishing on which actors are understood to potentially have conflicts that require management. The research undertaken in this thesis will explore this seemingly limited conceptualisation, examining if and how the COIs of other actor groups are managed, and the potential implications of this.

As this chapter has demonstrated, COIs present medical/health research and resulting journal publications with a problem. Bias can affect both the conduct of research and its presentation within the journals. For the integrity of the medical/health journal literature to be restored and protected, COIs need to be effectively handled, and it is thus necessary to understand how COIs are currently being managed (or not), why such approaches are favoured, and what alternatives might warrant further explanation. Previous studies (as discussed in Section 2.5.2) have quantitatively analysed journal guidelines, offering useful insights into the increase in their use over time, and how successful they are, as well as some of their weaknesses. The research presented in this thesis builds on this, taking a qualitative approach in order to critically examine, in more depth, a wider variety of publishing policies and guidance on COIs, as well as 48 original interviews. This allow us to explore and develop a greater understanding of how COIs are conceptualised within the institutional environment of medical journal publishing. This includes the perceptions of those actors within that environment of what constitutes a COI, which actors can be conflicted and how such conflicts should be managed, as well as exploring

how such conceptualisations developed. This allows us to better understand the barriers to, and possibilities of, progress and change.

## **CHAPTER THREE: BACKGROUND**

### **Mapping the institutional environment of medical journal publishing**

#### **3.1 Introduction**

This thesis examines the conceptualisation of conflicts of interest (COIs) by the actors that comprise the peer reviewed medical and health journal publishing industry: ‘the institutional environment’ (Furusten, 2013). This kind of institutional environment ‘determines the conditions that organizations and their managers must adapt to and manage in order to be regarded as legitimate actors in the type of business they conduct’ (Furusten, 2013, p. 6). In the case of this research, the institutional environment is a broad sector, including: publishing houses, professional associations, medical writing companies, corporate actors interested in medical research (in this thesis, the focus is on companies from the pharmaceutical and tobacco industries, given concerns about COIs relating to these sectors in particular), and the individuals working within each of these sectors (such as editors, publishers, medical writers, medical/health researchers/authors, and those involved in publications within the pharmaceutical companies). Drawing on information gathered through analyses of business reports, industry news articles and interviews, this chapter seeks to map out this environment. It provides a critical introduction to the organisations and businesses involved in developing policies and guidance on the management of COIs in medical journals, and the key individual agents working within them. In doing so, it highlights how the relationships between the different actor groups can present potential COIs, such as the reliance of many journals financially on income from the pharmaceutical industry (see Section 3.2.3). These conflicts have the potential to impact on the reliability of such actors’ efforts to effectively manage COIs.

The chapter begins, in Section 3.2, by introducing the main actors involved in peer reviewed medical and health journal publishing. This allows the reader to develop a picture of the field, and also contextualises the examples of journal policies and practices selected for analysis in this thesis (as discussed in Chapter Four, Section 4.4). The key policies and guidance relating to publishing ethics (in particular, on COIs) that have been developed by the sample organisations, form part of the data analysed in this research, as do interviews with the individual agents. Section 3.4 offers an outline of these policies and guidance in order to provide readers with a greater understanding of the material produced by these organisations to manage COIs, and offers a context through which to understand the methodology, results and discussion chapters.

## **3.2 The key actors in medical journal publishing**

The following section provides an overview of the main actors involved in the institutional environment of medical journal publishing, both in terms of the organisations and the individual actors. Demonstrating the size of the medical journal publishing industry and the ways in which actors within it interconnect, this chapter provides some important contextual information for the results and discussion chapters. This section also highlights some of the interests of the actors involved, which may pose COIs. This shows that potential COIs exist at a number of different levels of the business, and that the very actors involved in developing the guidance and policies that exist to manage COIs can themselves be conflicted; this may result in narrow interpretations of COIs.

### ***3.2.1 Publishing houses and peer reviewed medical/health journals***

Medical/health journals are owned by a variety of organisations, such as: commercial publishers, commercial societies and associations, and not-for-profit organisations (for example, universities or professional societies). The publishers whose journals were included in the data sample for this thesis are: Elsevier, Springer, Wiley-Blackwell, Taylor and Francis (owned by Informa) and Oxford University Press (see Section 4.4.1, Chapter Four for more on the data

sampling for this research). Societies and associations that own journals may themselves publish them, or alternatively employ commercial publishing companies to manage the process. The majority of journals are published by a few large, multinational publishing companies, with the top five publishers producing almost 35 per cent of journals (Ware and Mabe, 2015). These large publishers publish across a range of disciplines and produce other products besides journals, including books and, increasingly, electronic platforms such as e-books, smart phone apps, online videos and interactive learning resources.

While the publishers' websites and financial reports do not state how much of their overall revenue is generated specifically from journals, Ware and Mabe (2015) estimate that the annual revenues generated from English language STM journal publishing in 2013 were roughly US\$10 billion, within a wider STM publishing market worth around US\$25.2 billion. Other STM revenue sources include book publishing, worth approximately US\$5 billion annually (Ware and Mabe, 2015). This compares with the publishing market for the social sciences and humanities, which in all languages is estimated to be US\$5.2 billion dollars (Esposito, 2014).

One of the main revenue streams generated by journals is institutional subscriptions, which are sold in packages to library consortia; due to non-disclosure agreements signed by the libraries, the exact amount paid by them for these is hard to uncover (Van Noorden, 2013). However, a 2012 memo from Harvard University's Library gave an indication: it stated that they were paying US\$3.5 million per year to publishers for access to journals. This memo also stated that publishers were drawing profits of 35 per cent or more from journals, with prices for access to online articles from two major publishers increasing by 145 per cent over the preceding six years, and some journals costing as much as US\$40,000 (The Faculty Advisory Council, 2012). Some revenue is also generated from individuals purchasing subscriptions and downloading single articles, with Elsevier generally charging US\$31.50 per article (Elsevier, 2015). Libraries and individuals have protested over the cost of journal subscriptions,



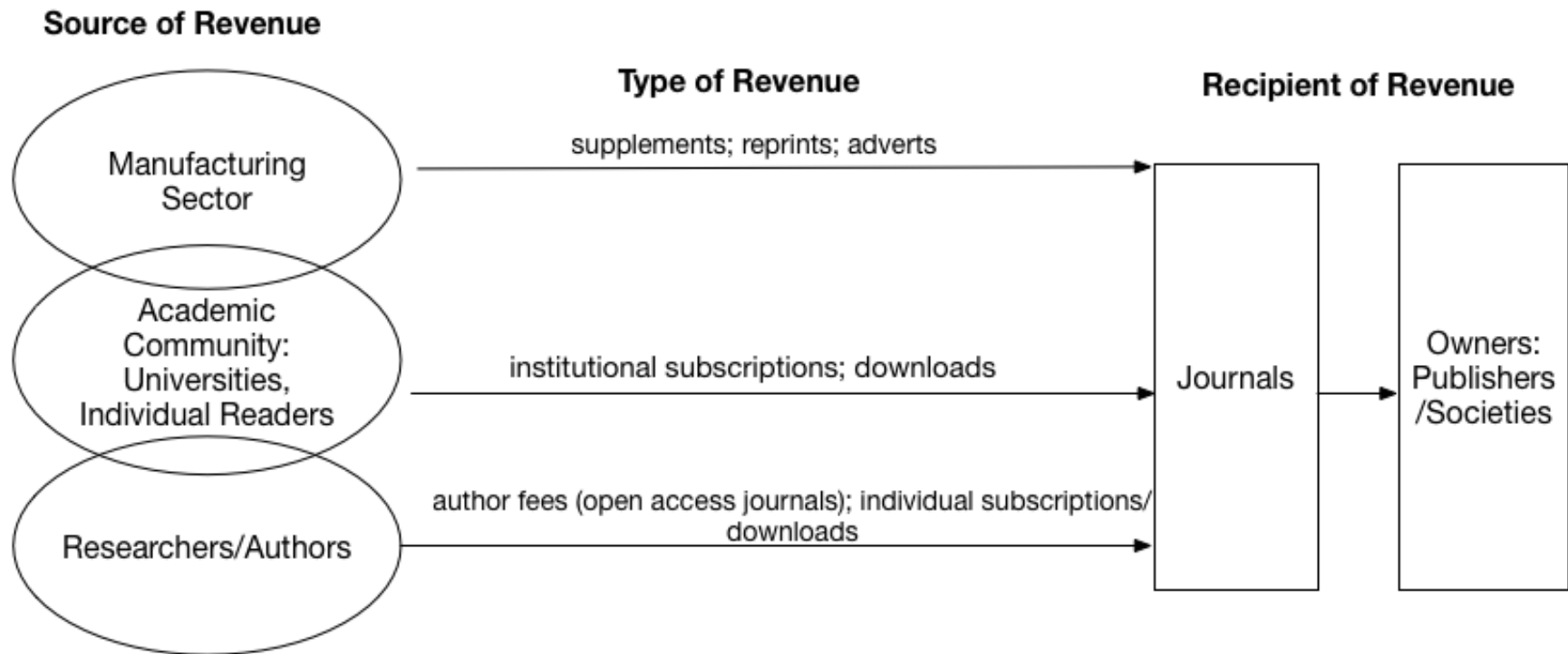
particularly Elsevier's, which has frequently been singled out for its prices that have been viewed as being exorbitant.<sup>4</sup> Recently, the editors of *Lingua* quit in protest over the fees Elsevier charges for access to the journal, and its oblique pricing system (Greenberg, 2015, Jaschik, 2015). A boycott of Elsevier by Dutch universities (Kingsley and Harnad, 2015) resulted in the publisher agreeing to make 30 per cent of the research published by Dutch researchers in Elsevier journals open access by 2018 (Bohannon, 2015).

Other sources of revenue for medical journals include reprints, supplements and advertisements (often paid for by companies in the manufacturing sector), although how much journals earn from such specific revenue sources is hard to determine as they do not routinely report this information in their annual reports (Lexchin and Light, 2006). Revenue from manufacturers can present potential COIs for the journals (and their owners and publishers), as discussed in Chapter Two, Section 2.3.1.2, and Chapter Five, Section 5.4. I constructed Figure 3.1 to illustrate the sources and types of revenue received by the journals, as discussed in this section.

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<sup>4</sup> See, for example, the website 'The Cost of Knowledge', signed by 15512 people, at: <http://thecostofknowledge.com> (accessed 22<sup>nd</sup> January 2015).

Figure 3.1: Journal revenue streams



(Original diagram.)

Many public sector funding agencies globally now require that articles resulting from research they have funded be made Open Access (OA) (for example, the Medical Research Council and the Wellcome Trust in the UK, and the National Institute of Health in the US).<sup>5</sup> This allows such articles to be accessed without payment. The sharing of data also arguably leads to greater scientific transparency and, it has been argued, progress (Parker, 2013). There are several different OA models. Some of these require authors to pay a fee (referred to as an ‘article processing charge’). Gold OA (including full and hybrid journals) means that articles are fully OA upon publication, with authors paying a fee; the Open Archives or Delayed Free Access models see the publisher making some or all of the final versions of articles available after a period of time has elapsed; and Green OA allows authors to post a pre-print version of the manuscript on a website or in an institutional or subject-area repository, which can be viewed after a certain period of time has elapsed (Hubbard, n.d., Björk, 2014). Other OA journals may be funded through advertising or sponsorship from the manufacturing sector, internal subsidies from their publisher or external grants from foundations and other philanthropic organisations and individuals, or through sales of printed copies. Some institutions fund university presses that publish OA journals (Swan and Chan, 2012, Crow, 2009).

Open access journals pose some new ethical challenges (Parker, 2013). These include the emergence of further sources of potential COIs (Salem and Boumil, 2013): for example, those journals that rely on author fees may be less stringent in their requirements for articles they publish (including managing authors’ potential COIs) (Salem and Boumil, 2013), and there has been a rise in so-called ‘predatory’ OA journals, which present themselves as legitimate journals, but in reality have low standards of selection, providing the authors (who are recruited via mass, indiscriminate emails) pay the substantial fees

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<sup>5</sup> For a list of global OA repository mandates and policies adopted by universities, research institutions and research funders, see: [http://roarmap.eprints.org/view/policymaker\\_type/funder.html](http://roarmap.eprints.org/view/policymaker_type/funder.html) (accessed 17th January 2016).

(Beall, 2012, Beall, 2013).<sup>6</sup> This is discussed in more detail in Chapter Five, Section 5.4.2. Of the journals in my data sample, only two, *PLoS Medicine* and *BMC Medicine*, are fully OA.

### **3.2.2 Editorial staff**

My interview sample included representatives working in a range of roles at publishing houses and journals. The editorial departments within publishing houses are typically managed by publishers and editorial directors. Their roles include overseeing the publication programmes, and managing long- and short-term goals for their company. They may also work on individual publications as well as other media, and manage editorial ‘best practice’, which can include the publisher’s ethical policies and procedures.

Editors-in-chief (EIC) lead journals, with ultimate responsibility for what is published (made on the basis of peer review reports and consultations with associate editors). Larger journals, such as *The Lancet* and the *BMJ* may also have executive or senior editors who perform similar roles to the EICs, heading up more niche, speciality journals which are published under the ‘parent’ journal’s name. The roles and responsibilities of EICs (and senior/executive editors) can overlap with those of the publisher, depending on the relationship between the two. EICs will approve the journal’s budgets, provide the owner with reports on the journal’s activities and represent the editorial board in negotiations with the journal’s publisher (see Council of Science Editors, 2012a for details of their typical roles and responsibilities). According to the Council of Science Editors, an EIC should also be responsible for developing and enforcing their journal’s policies, including those on ethical issues such as the management of COIs for authors and reviewers (Council of Science Editors, 2012a). On larger medical journals, EICs are generally employed full time. However, EICs who work on smaller speciality journals are often employed part-time, working concurrently

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<sup>6</sup> See Beall’s list of OA predatory journals at: <http://scholarlyoa.com/publishers/> (accessed 17<sup>th</sup> January 2016).

in other roles, for example as physicians or researchers; they will typically have been appointed on the basis of their expertise in the relevant clinical field and will not necessarily have professional journal publishing experience, beyond authoring/reviewing articles.

Managing editors (MEs) may be employed directly by journals or work within publishing houses; alternatively, journal management may be outsourced to external companies who employ freelance staff to undertake this work. MEs are typically responsible for running the journal's editorial office, and will look after the day-to-day management of the journal (Smith, 1997, Hannan, 2002, Kerr, 2014). There is much variation in the specific duties and levels of responsibility that MEs have, depending in part on the level of involvement of the EIC and the publisher (Smith, 1997). Duties may involve the checking of proofs, budgeting, managing the review process, and contributing to publication and marketing decisions and longer-term planning surrounding the content of the journal (Smith, 1997, Hannan, 2002). Associate editors are senior members of editorial boards who are involved in the reviewing and decision processes.

### ***3.2.3 Manufacturing sector companies***

Another organisational actor within the medical journal publishing industry, which is of relevance to this research, is the manufacturing sector. This comprises those companies that are involved in the medical research surrounding their products. This thesis focuses on the pharmaceutical and tobacco industries for reasons outlined in Chapter One, although other relevant examples include the biotechnology, medical device, and food and drink industries.

Pharmaceutical and tobacco companies employ in-house staff and fund external scientists to conduct research relating to their products, the results of which are often published in medical journals. These companies (particularly those in the pharmaceutical sector) may also have departments or individuals

that are responsible for overseeing the publications that result from this research; for example, GlaxoSmithKline has a department of Medical Communications Quality and Practice, and Pfizer has a Publications Management team. There is very little information available on the roles of the staff on such teams, and job titles vary widely. However, some insight is provided through analysis of the job descriptions available on websites such as LinkedIn and sites aimed at medical communication professionals (e.g. Network Pharma, 2014, The Publication Plan, 2014), as well as through interviews with individuals who work in such roles. The tasks of those working in this area typically involve: monitoring publication programmes; managing the involvement of external medical writing companies (discussed in Section 3.2.4); and developing and ensuring adherence to company publication policies/guidance and agreements, including on COIs, for researchers working with the company. Such companies may also have in-house publication planning and medical writing teams, which develop publication plans and work on journal articles, as well as other communications.

Manufacturing sector companies also provide a vital source of income to many medical and health journals, through purchasing reprints of articles, sponsoring supplements and buying advertising space; some journals are financially dependent upon these revenue streams to survive, and can charge high fees for them (Elliott and Landa, 2010) (see Chapter Two, Section 2.3.1.2 for more on this). While many individuals and organisations may also purchase reprints of articles (for example, to use as an educational tool by giving out copies at conferences), the pharmaceutical industry is thought to be the main purchaser, using them as marketing material (Handel et al., 2012, Smith, 2006). Companies also often fund journal supplements that have been developed out of symposia that they have funded, containing articles about drugs they have sponsored (see Section 2.3.1.2, Chapter Two). Again, journals can charge a large fee for publishing such issues (Smith, 2003).

### ***3.2.4 Medical writing companies***

Medical writing companies (MWCs) offer a variety of consultancy services to the pharmaceutical industry, such as public relations and advertising, regulatory affairs (for example, developing clinical trial documents and new drug applications), and working on publications (including conference presentations and journal articles) (Moon, 2015, Adamson et al., 2008). They can therefore be involved at all stages of a drug's development. While these companies are involved in the medical sector (working for the pharmaceutical and biotechnology industries), the tobacco industry has employed law firms in a similar fashion, using them to liaise with scientists and organise publications (Drope and Chapman, 2001, Muggli et al., 2003, Hong and Bero, 2002, Rampton and Stauber, 2002) (see Chapter Two, Section 2.4 for more on this).

Some MWCs are subsidiaries of bigger global communication, advertising or PR groups. For example, WPP, the world's largest communications group, has over 150 companies providing services in an array of fields including Healthcare and Communications. This includes the Ogilvy Group that has a division, Ogilvy CommonHealth Worldwide, which offers 'scientific communications and publications services (WPP, 2011a). Sudler & Hennessey also comes under WPP's Healthcare and Communications group. One of the world's leading healthcare communication firms (WPP, 2011b), subsidiaries of Sudler & Hennessey include IntraMed Educational Group and Current Medical Communications.

Other MCCs are independent organisations. One such company, Complete Healthcare Communications, founded in 1996, is a 'strategic medical communications agency that specialises in publication planning' (Complete Healthcare Communications, 2009). Another independent MWC, Scientific Therapeutics Information, was established in 1985 and is a 'full-service medical publishing group' and promises to 'develop meaningful, motivational messages that differentiate your product from the rest of the industry ... if you want to create something, you have to be creative' (Scientific Therapeutics Information

Inc., n.d.). Both Complete Healthcare Communications and Scientific Therapeutics Information have been involved in ghost-writing scandals; see Chapter Two, Section 2.4.

Some pharmaceutical companies and big publishing houses have medical writing and publication planning teams in-house, or own MWCs. For example, Wolters Kluwer launched inScience Communications in 2010 (Wolters Kluwer, 2010), which offers publication planning and medical writing services (inScience Communications, 2014); this is now part of Springer Healthcare, 'a leading global provider of clinical publications, scientific communications, and medical education' (Springer Healthcare, 2010). Elsevier used to own Excerpta Medica (now owned by the pharmaceutical consultancy organisation Adelphi Group, which in turn is part of the advertising conglomerate Omnicom Group). At the time of Elsevier's ownership, in the mid-1990s, Excerpta Medica was involved in a controversy surrounding the ghost-writing of articles for the pharmaceutical company Wyeth (Elliott, 2004) (see Chapter Two, Section 2.4 for more on this). During this period, Excerpta Medica also published several 'fake journals' on behalf of Merck, which were reported as having the look and feel of peer reviewed publications (although they were not peer reviewed), and which presented data favourable to Merck (Grant, 2009a, Grant, 2009b).

### ***3.2.5 Medical/health authors***

One of the actor groups involved in medical journal publishing that will perhaps be most familiar to readers of this thesis is the authors of the articles published in the journals. Since most readers will likely fall into this category, little further explanation on the role of this group is perhaps necessary. However, it is worth underlining precisely who counts as an author as this remains a contested area in medical journal publishing in at least two ways. Firstly, because of the academic, social and financial benefits conferred by authorship in academic journals, individuals connected to a research project may request to be named on articles of which they have had little or no substantive input. This practice



has been termed ‘guest’ or ‘honorary’ authorship. The second highly contested issue surrounding authorship is precisely the opposite problem, whereby individuals who have been involved in the research and write-up are not named for strategic reasons: this practice is referred to as ‘ghost authorship’, and is discussed in Chapter Two, Section 2.4. To deal with these issues, the professional publishing associations (an overview of which is given in Section 3.3) have attempted to clarify what needs to be done to acquire authorship status, with the International Committee of Medical Journal Editors’ (ICMJE) criteria appearing to be the most widely used by medical journals (see ICMJE, 2015a). These recommend that authorship be based on the following:

- ‘Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.’

### ***3.2.6 Medical writers***

Medical writers produce scientific documents on behalf of MWCs (as discussed in Section 3.2.4), for a wide range of publications, including medical journals. Their job is to present the information they are provided with by researchers in an appropriate format for its audience. Their role, however, often goes beyond simply writing the articles: medical writers can be involved with the development of the communication strategy and publication plan for a drug, which is produced in tandem with its clinical development and marketing (Moon, 2015). The involvement of medical writers has thus been contested, with concerns that they help to market the products about which they write (Sismondo, 2009, Sismondo and Doucet, 2009, Sismondo and Nicholson, 2009, McHenry, 2010, Moffatt and Elliott, 2007, Hendrick, 2011).

In the majority of publishing policies and guidance analysed in this research, medical writers are generally considered to be one sub-category of contributors, with no distinction made between the different types. The commonly used authorship criteria by the ICMJE, referred to in Section 3.2.5, are quite stringent regarding who qualifies as an author. These state that those who are involved in medical journal articles, but who do not meet these criteria, should be labelled ‘contributors’. This includes those involved with ‘acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading’ (ICMJE, 2015d, p. 3). However, given the prominence of the debate in the research literature over the role and influence of medical writers (e.g. Górski and Letkiewicz, 2010, Woolley, 2006), and the fact that they have their own professional associations such as the European Medical Writers Association (EMWA) and the American Medical Writers Association (AMWA) representing them, it should be noted that they are discussed as a distinct actor group in this research.

### **3.3 The professional associations representing these actors**

Within Furusten’s ‘institutional environment’, there are actors that he refers to as ‘others’ (2013). These actors inform how other key organisations within that environment should work and certain functions be handled, and their task is to produce information and rules about organisations. There are a number of professional associations that represent and provide resources for those working directly in the various sectors comprising the medical/health journal publishing field, which constitute these ‘other’ actors. The resources they provide include the provision of guidance and policies on best ethical publishing practices, such as on how to manage COIs. The associations listed in this section were identified through being cited in interviews and/or were referred to in the journal or publisher policy documents that formed part of the data corpus of this project. The policies and guidance developed by these professional associations

also formed part of the data analysed in this research (see Chapter Four, Section 4.4.1), and an overview of the resources they offer members on ethical issues is given in this chapter in Section 3.4.4. The following section, based upon analysis of websites, discussions in interviews and attendance at conferences and meetings, provides an outline of these associations: their main purpose, the resources they provide and their structure. These associations play a significant role in the construction of issues (including on COIs) through their policies and guidance, with other actors, such as publishers and journal editors basing their own understandings on these. Publishers and editors develop their own policies and guidance based on these, which in turn inform authors, reviewers and readers. These associations' internal accountability is worthy of consideration, because the interests of those who run them and their members' may impact on the ways in which they present issues and how they should be managed. Their own COIs could affect how they construct the debate around COIs itself.

There are several professional associations that have been set up to represent those actors working on peer-reviewed journals. These include: The International Committee of Medical Journal Editors (ICMJE), the Committee on Publication Ethics (COPE), the World Association of Medical Editors (WAME) and the Council of Science Editors (CSE). The oldest of these associations are the CSE (originally the Conference of Biology Editors), which was formed in 1957, and the ICMJE, established in 1979 as the 'Vancouver Group'. The majority of these associations, however, were set up in the 1990s and 2000s, reflecting the growth in the medical journal publishing industry in this period. There are also professional associations that represent other subsections of medical journal publishing, such as medical writing companies.

### ***3.3.1 The International Committee of Medical Journal Editors (ICMJE)***

Founded in 1979, the ICMJE is a key professional publishing association and perhaps the most prominent; its guidance on authorship, found in its Universal Requirements for Manuscripts, are the most commonly used by medical and

health journals.<sup>7</sup> Its COI disclosure form (or derivations of it) is frequently used by journals in retrieving information from authors. It currently has 14 general medical member journals (see ICMJE, 2015b for an up-to-date list of members). Its website states that it is not an 'open membership' organisation (ICMJE, 2015b), so while many other medical journals (both general and specialist) have signed up to demonstrate their adherence to the ICMJE's recommendations (see ICMJE, 2015c for a list of these journals), they have no input into the recommendations as they are not 'members', and the organisation does not consult externally. The association occasionally accepts new members if they feel such additional journals or organisations would add a new and needed perspective (ICMJE, 2015b). However, despite the organisation being so influential in the field, the ICMJE's website gives no indication of how decisions are made. The management of the organisation is opaque (for example, there are no records of minutes of meetings on its website), and it has no formal structure. There is no COI disclosure of its members available on its website. Seven journals in my sample are members of the ICMJE, while another eight are signatories (but are not members).

### ***3.3.2 Committee on Publication Ethics (COPE)***

COPE is a UK-based charity. Formed in 1997 as an organisation for biomedical journals (COPE, n.d.), it now serves journals from all disciplines. COPE has a formal structure. It has a council, the positions of which are fixed term with elections held annually, and in which the organisation's members can vote; it is therefore a more democratic and transparent organisation than the ICMJE. COPE is governed by a Trustee Board comprised primarily of editors and publishers,

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<sup>7</sup> A list of those journals subscribing to the ICMJE's recommendations can be found at <http://www.icmje.org/journals-following-the-icmje-recommendations/> (last accessed 21<sup>st</sup> June 2016). Thirteen of the journals in my sample (eight from my high IF journals and five from my 'other' journals) are listed as following the recommendations.

as well as a charity solicitor.<sup>8</sup> Their COI declarations are provided on its website (COPE, 2016a). According to one interviewee, who was at the time sitting on the COPE council, the organisation began as a small group of EICs getting together to discuss the handling of particular ethical cases. Now, with over 9,000 members (primarily publishers, EICs and MEs), its quarterly meetings provide a forum where ethically problematic issues can be discussed and advice shared collectively. Fourteen of my sample journals (five from my high impact factor (IF) group and eight from my 'contentious cases' group) are members of COPE. The organisation has come under fire in the recent dispute between *The Lancet* and the *BMJ*, with the former criticising it for its inability to effectively regulate journals accused of publishing malpractice (see Chapter One, Section 1.1).

### **3.3.3 World Association of Medical Editors (WAME)**

Set up in 1995, WAME is a not-for-profit voluntary organisation, governed by a Board of Directors and six committees. Its aim is to support members and promote ethical scientific publication. According to one interviewee who sits on one of the committees, it was set up to provide a more egalitarian and global alternative to the ICMJE; like COPE, it is more democratic, with its officers elected by its members. Its Executive Board, Directors and Committee members are listed on its website (WAME, 2016c) and are comprised of editors, publishers and medical writers. Unlike COPE, however, these individuals' COIs are not declared. With more than 1,915 members representing over 1,000 journals from 92 countries, it is a much larger organisation than the ICMJE, with all decision-making editors of peer-reviewed medical journals, and 'selected scholars in journal editorial policy and peer review' eligible to join (WAME, 2016a). It is a 'virtual' organisation which does not have formal meetings. Its original aim was to develop an online training programme for editors; it now provides a listserv for members, as well as developing policies and resources on ethics (e.g. WAME

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<sup>8</sup> A list of COPE's Trustees can be found at <http://www.publicationethics.org/about/trustees> (last accessed 22nd June 2016).

et al., 2013, WAME Editorial Policy and Publication Ethics Committees, 2009, WAME Editorial Policy Committee, 2007, WAME Editorial Policy Committee, 2005a, WAME Editorial Policy Committee, 2009, WAME Editorial Policy Committee, 2005b). The editors of nine of the journals in my sample belong to WAME; of these, all are from my high IF sample, other than *AJOG*.

### **3.3.4 Council of Science Editors (CSE)**

The Conference of Biology Editors, established in 1957, became the Council of Biology Editors in 1965; shortly thereafter it began representing a wider range of scientific fields. It changed its name again in 2000 to the Council of Science Editors (CSE). A global organisation targeted at the natural sciences, it has over 800 members who work in various editorial capacities on scientific communications. It is comprised of a number of committees (made up primarily of editors and medical writers) and its aim is to provide networking and educational opportunities for career development (including seminars on COIs held at its annual meeting), and resources to assist in the implementation of best editorial practice (including on the management of COIs), such as its White Paper, developed by its Editorial Policy Committee (CSE Editorial Policy Committee, 2012). Its members elect the board of directors<sup>9</sup> who are also a mix of editors, medical writers and others working within the medical publishing field (in marketing and product development roles). Their COIs are not declared on the website. Eleven of my sample journals are members of CSE (seven high IF journals and five 'contentious case' journals).

### **3.3.5 Medical writers' associations**

There are also professional associations that have been set up to represent medical writers. The most established and prominent of these are the European Medical Writers Association (EMWA) and the American Medical Writers Association (AMWA). The former, a not-for-profit organisation, was established

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<sup>9</sup> See <http://www.wame.org/about/wame-executive-board-and-committees> for a current list of board and committee members (last access 21<sup>st</sup> June 2016).

in 1989, with its first official meeting in 1992 (European Medical Writers Association, 2015a). It now has more than 1,000 members who work as medical writers in-house or as freelancers for pharmaceutical companies, MWCs, research institutes and in the field of scientific journalism (Ibid). Reflecting the global nature of the medical writing trade, members of EMWA are from 39 countries, including 12 outside Europe (Ibid). Its stated aim is to offer professional development to members in order to promote high standards in medical writing (European Medical Writers Association, 2015a). Its website says that it is an organisation 'run for its members by its members' (European Medical Writers Association, 2015a), and its officers (elected by the members) are medical writers from across the different types of companies engaged in such work. Their COIs are not declared. AMWA, its North American counterpart, was established in 1940; it was initially set up to cater for physicians who were also writers or editors (American Medical Writers Association, 1990). However, its membership became increasingly comprised of those specifically pursuing careers in medical writing (Losi, 1987). Similar to EMWA, it has a global membership, with almost 5,000 members in the US, Canada and 30 other countries. Like those who belong to EMWA, members of AMWA also work for pharmaceutical companies, universities and medical schools, hospitals, not-for-profit organisations, government agencies and journals (American Medical Writers Association, 2015). Its structure comprises a Board of Directors, Executive Committee and National Officers (elected by the members). COIs are not declared on its website.

### ***3.3.6 Other associations***

The International Society of Publication Planners (ISMPP), a not-for-profit, professional member association, was formed in 2005 and now has a membership of over 1,400 individuals, consisting of actors involved in the publication of medical research (ISMPP, 2011). These members come from the manufacturing sector (such as pharmaceutical, biotechnology and device companies), MWCs, publishers and editors (ISMPP, 2011). Its governing board

is elected and consists of a number of individuals from the pharmaceutical industry and medical writing companies. Its website states that its aim is to improve the integrity, transparency and standard of medical publishing, and to educate those working in medical publishing, in order to advance the medical publication profession globally in terms of standards and best practice (ISMPP, 2013). According to one publisher who was interviewed as part of this research, its formation was an attempt to proactively improve publication practices across the pharmaceutical industry and rebuild reputations after high profile cases involving the hiding of data.

The Medical Publishing Insights and Practices Initiative (MPIP) was established in 2008, with the aim of improving trust, transparency and integrity in the publishing of industry-sponsored trials (MPIP, 2015). Its website states that it is a collaboration between ISMPP and various pharmaceutical companies (Ibid). Given that ISMPP itself also consists of these same pharmaceutical companies, the difference between the two associations is not entirely clear. MPIP's website also says that the organisation aims to promote better partnerships between research sponsors and journals in order to improve standards in medical publishing and increase access to research results (Ibid). As such, it has teamed up with editors from leading journals, for example from *Annals of Internal Medicine* and *The Lancet* (Mansi et al., 2012), to produce various recommendations on how certain issues relating to publishing ethics can be improved. The output of these collaborations is discussed in Section 3.4.5.

### **3.4 Managing conflicts of interest: organisational actors' documentary guidance**

The following section introduces the multiple resources that have been developed to manage COIs by the organisational actors discussed in Section 3.2 of this chapter. These materials form part of the data analysed in this research (see Chapter Four, Section 4.4.1), the results of which are given in Chapters Five, Six and Seven. These resources contribute significantly to the very



conceptualisation of COIs within the institutional environment of medical journal publishing – what interests constitute conflicts, and who might be conflicted (see Chapter Five) – and also explain to actors how conflicts should be dealt with (see Chapters Six and Seven). The purpose of presenting them here is to offer the reader a context for understanding the following chapters, as well as demonstrating the vast array of resources available, and their variability in terms of the quantity and the format of resources.

### ***3.4.1 Publishers' contribution***

My data sample demonstrates that publishers provide varying levels of information to their users on publishing ethics in medical research and journal publishing, including on COIs. For example, Wiley has produced an extensive, 56-page document on all areas of publishing ethics for authors, editors and reviewers, including a section on COIs (Deakin et al., 2014); it also has a helpdesk that editors can email with queries. Springer has also produced fairly detailed guidance for authors and editors, which contains discussion on COIs. Elsevier has a great deal of information available on its website for authors, editors and reviewers on ethics, mainly in its Publishing Ethics Resource Kit. Its resources include a COI 'fact sheet' (Elsevier, n.d.). However, Elsevier's guidance on ethics can be somewhat difficult to navigate as it is contained in various different sections of its website. Other publishers, such as Oxford University Press and Taylor and Francis, offer sparse information on ethics (including COIs) to their users; what they do provide can also be difficult to locate. Table 4.4 (Chapter Four, Section 4.4.1) lists the guidance provided by the publishers that was included in the data sample for this research, along with its format and target audience.

### ***3.4.2 Guidance provided by journals***

As with the publishers, the journals in my sample also provide widely differing amounts of guidance to their users on COIs. This guidance is available in their various online and published policies, such as their 'Instructions for Authors',

disclosure forms and submission processes. Some, such as *PLoS Medicine* and the *BMJ* provide extensive resources on publishing ethics, including on COIs for editors, authors and reviewers, while other journals, such as *Clinical Therapeutics* and *Birth Defects Part B*, provide only a brief definition of COIs. Appendix I shows the resources provided by each journal in my data sample on COIs that was included in the analysis. It demonstrates the multiple formats in which guidance is available, and the various different locations where it is stored, which journal users are expected to seek out and follow.

### ***3.4.3 Guidance provided by the professional publishing associations***

The ICMJE's 'Uniform Requirements for Manuscripts Submitted to Biomedical Journals' (URM), first produced in 1978 as a way of standardising manuscript format and preparation across journals, outlines the organisation's views on what constitutes best practice in medical journal publishing, with the ethical standards that should be met in the conducting and reporting of research and other material published in medical journals. The latest version of the URM (renamed 'Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals'), was published in December 2015 (ICMJE, 2015d).<sup>10</sup> It contains guidance on a range of ethical matters relating to medical journal publishing, including authorship/contributorship, editorship, peer-review, COIs, clinical trial registration and reporting requirements. With regards to the advice on COIs, it summarises what these could constitute and how they should be reported for authors, peer reviewers, and editors and other journal staff. The ICMJE has also developed an author COI disclosure form in an attempt to standardise this process.

COPE offers various resources to editors and publishers relating to publishing ethics, including: flowcharts that depict the steps journals should take

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<sup>10</sup> The 2013 edition was included in the data sample in this research, as this aspect of the research was conducted prior to 2015. However, there have not been any changes made in the latest edition to the sections relevant to this research.

if certain issues arise, including two which describe what to do if readers suspect undisclosed COIs (Wager, 2013a, Wager, 2013b); ethical guidance (COPE, 2013, COPE, 2014); 11 e-learning modules (including one on COIs); a newsletter; and codes of conduct which members are expected to follow (COPE, 2011, COPE, n.d.), and which include some limited guidance on the management of conflicts of interest. In addition, details of cases heard by COPE at its meetings, together with their outcomes, are put on a database; this information can then be accessed by members in order to see how particular situations are best handled.

Journals can submit ethical cases to WAME's Ethics and Policy committee, even if they are not WAME members, which will provide a free consultation. Details of the cases are anonymised and discussed by the committee members via email; occasionally they are referred on to COPE for additional consultation. These cases and their corresponding advice are then summarised on the organisation's website, which the member journals have access to. Therefore, as with COPE, members can see how particular issues could be best handled. WAME also has a listserv where members can discuss issues amongst themselves (and cases are sometimes put on the listserv in order to acquire feedback from a wider group), and according to interviewees involved with the organisation, this is what WAME is primarily used by journal editors for. It has also developed several publication ethics policies, including one on COIs. This policy defines COIs and offers suggestions on how journals should manage them (WAME Editorial Policy and Publication Ethics Committees, 2009). Other policies and guidance cover how relationships between editors and journal owners should be handled (WAME Editorial Policy Committee, 2009), ghost-writing (WAME Editorial Policy Committee, 2005a), authorship (WAME Editorial Policy Committee, 2007) and clinical trial registration (WAME Editorial Policy Committee, 2005b).

The CSE produces a quarterly publication, *Science Editor*, which provides a forum for members to exchange information regarding publishing in the natural sciences. There are also a number of committees, including an Editorial

Policy Committee, that have produced policies and guidance, including step-by-step information on how journals could develop or revise their COI policies (Council of Science Editors, 2005), based on their analysis of procedural, ethical, legal, and economic policies, relating to the editing, review and publication of manuscripts in books and journals. These aim to bring clarity to the often vague and opaque business of scientific publishing. The CSE's Editorial Policy Committee produced an extensive White Paper (2012), which provides guidance on the responsibilities of actors within medical publishing (authors, editors, peer reviewers, research sponsors and journal owners), including on how their COIs should be managed.

#### ***3.4.4 Guidance provided by trade associations representing MCCs and PPCs***

EMWA has produced a position statement on ghost-writing (European Medical Writers Association, 2015b) and has also published guidance on the responsible use of medical writers in peer-reviewed publications (Jacobs and Wager, 2005). The former advises medical writers to keep up-to-date with journal COI requirements; the latter also includes a section on the acknowledgement of medical writers and disclosure of their funding sources. AMWA offers an education programme, holds an annual conference, and provides its members with networking and job opportunities. It publishes the *AMWA Journal* and it has also produced a Mission Statement which advises on how medical writers should be acknowledged (Hamilton and Royer, 2003). ISMPP has a Code of Ethics that provides guidance on the management and disclosure of COIs (ISMPP, n.d.), and the organisation was also involved in developing the *Good Publication Practice 2* (GPP2) guidance (Graf et al., 2009), which provide advice on the management of COIs, and the responsibility of medical writers in this regard.

### **3.5 Concluding discussion**

This chapter mapped the institutional environment of medical journal publishing, providing an insight into the key actors that comprise it, both at the organisational and individual levels. Section 3.2 described the activities involved

in key professional roles; these were the kinds of posts held by the individual actors interviewed as part of this research. It also outlined the main types of organisations involved: publishers, journals and manufacturing sector companies, while Section 3.3 offered an overview of the professional associations that represent them with regards to their journal publishing activities. Section 3.4 then proceeded to discuss the policies and guidance these actors have developed on publication ethics, in particular on COIs, which comprised part of the data used in this research. In doing so, this chapter provides readers with a framework through which to understand the following methodology, results and discussion chapters.

The plurality of actor groups comprising the institutional environment of medical journal publishing, and the multiple sources of guidance on COIs that are available from the organisations discussed, is demonstrated in this chapter. This posed a challenge for this project practically in terms of accessing and analysing all of the data, and presenting the results in a coherent fashion. It also, significantly, presents difficulties for the users of such guidance: they are faced with perhaps an overabundance of information and suggestions from different organisations, which is not always consistent, and there are no overarching, definitive policies. The results and discussion chapters analyse these numerous policies and guidance, looking at where they align and where they differ, alongside interview data, to determine how the field conceptualises both COIs and the ways in which they should be managed.

This chapter also demonstrates some of the ways in which the different actor groups are interconnected, and these relationships may themselves lead to potential conflicting interests. For example, some medical writing agencies are owned by pharmaceutical companies, and in some cases, medical writers are directly employed by them. The ability for such writers to maintain scientific rigour when developing manuscripts on behalf of these companies is therefore brought into question: they may, consciously or subconsciously, feel pressured to produce content favourable to their employer. Medical journals account for a

large amount of publishers' revenue, and therefore arguably publishers have a vested interest in maintaining these journals' profitability. Journals' receipt of revenue from manufacturing companies for publishing advertisements, supplements and reprints also presents a potential conflict for the staff working on them (see Chapter Five, Section 5.4.1).

This chapter looked at the professional associations and the guidance that they offer; this plays a significant role in informing the guidance and policies produced by the publishers and journals themselves, and the understandings of critical issues by those actors working within them. They therefore play an important role in the way in which the topic of COIs and its management is constructed. This chapter examined the structure of these organisations and their internal accountability, in order to consider whether the interests of those involved in them may impact on their presentation of issues.

Thus, this chapter demonstrates how conflicts potentially exist across multiple areas of the business of medical journal publishing, including, crucially, amongst the very parties responsible for managing COIs. In doing so, it provides readers with a context through which to understand the data presented in the results and discussion chapters. These conflicts are perhaps not always avoidable, but it is important to be aware that they may affect the very way in which the discussion around COIs and their management is presented. The results chapters assess the adequacy of this presentation, and its impact upon the way in which COIs are currently managed.



# CHAPTER FOUR: METHODOLOGY

## The Research Design

### 4.1 Introduction to the chapter

The purpose of this chapter is to provide an insight into the research strategy, methods and analytical approach taken to answer my primary research question:

*To what extent does the institutional environment of medical journal publishing inform actors' conceptualisation and management of conflicts of interest and their consideration of alternative approaches?*

By transparently detailing my research design here, and offering some methodological reflections, it is hoped that readers will be able to better understand the data presented in the following results and discussion chapters. The chapter begins, in Section 4.2, by providing a brief background to the funding of the PhD. Section 4.3 gives an overview of the process of ethical approval. Section 4.4 then outlines the epistemological philosophy that guided my approach: critical realism. This underpins my research question, as well as my sampling and analytical approaches, with the belief that while an objective reality does exist, the way in which people interpret it is always subject to their own experiences and subjectivities, and can never be entirely value-free. Section 4.5 describes the data sample used to explore the research problem, which was comprised of a combination of both policy and guidance documents from a range of organisations across the institutional environment of medical journal publishing, and transcripts from interviews conducted with 48 actors working in a variety of organisations and roles. It further outlines the process that I followed in collecting these data. Section 4.6 describes the analytical approach that was taken, which involved thematic analysis, and the method of conducting this analysis to produce the results explored in the subsequent chapters. Finally, Section 4.7 discusses the process of writing up the thesis.



## 4.2 Background to the PhD

This PhD was an ESRC CASE project (Grant number ES/I030735/1). Prior to commencing my research studies, I worked in the medical publishing industry, and I continued to do part-time freelance publishing work for the duration of my PhD, including as an editorial assistant on a medical journal, and conducting a six-month publishing ethics consultancy for a U.S.-based science publisher. The original title of this PhD was 'Communication Ethics in Medical Journal Publications', and was initially based in the Sociology department in the Faculty of Humanities and Social Sciences at the University of Strathclyde. Due to organisational changes, I transferred at the end of 2011 to the School of Social and Political Science at the University of Edinburgh, where I was based in the Global Public Health Unit within the Social Policy department. It was originally intended that the studentship would entail several extended placements at the CASE partner – the *British Medical Journal (BMJ)* – with participant observation comprising a substantial part of the data-gathering process. I spent two one-week placements there, which gave me a valuable insight into the running of a high impact factor, general medical journal, and allowed me the opportunity to publish with them (see Hendrick, 2011). However, as the project progressed and my research questions were refined, I decided that they would be better answered by looking at the management of COIs in the wider institutional environment of medical journal publishing, rather than focusing on just one journal. My research was therefore instead primarily conducted at the university.

My professional background meant that I had a dual identity when conducting this research: I was both an insider (as someone who worked in medical publishing) and an outsider (a researcher looking critically in at industry practices), and this likely had an impact on my research design. For example, the former meant that I came to my project with an extremely well-developed understanding of the publishing industry – its working practices and

processes – and this resulted in my being comfortable and confident when speaking to those working within it. This perhaps encouraged me to conduct interviews as part of my process of data collection (see Section 4.6.2). It also meant that I had already established contacts who could offer me information on the practices under study, which both expanded my knowledge and provided insights for my research. I was further able to use my ‘insider identity’ to access interviewees, who it is likely felt more comfortable speaking to someone they felt was ‘one of them’ rather than to a researcher they believed was looking critically, and perhaps negatively, at their work. The fact that the project was supported by the *BMJ*, which I mentioned in approaches to interviewees, may also further have encouraged them to respond more positively to my requests to speak to them. Hirsch (1995) has written that studies benefit from a researcher’s prior knowledge of their field or topic – what he refers to as their ‘street smarts’ (1995, p. 73). He argues that personal knowledge and connections can lead to a study that is more authoritative and carries greater weight. Hirsch also suggests that such ‘street smarts’ can enable researchers to gain access to interviewees. I felt overall that my ‘dual identity’ benefitted the research; however, it also undoubtedly presented some challenges. For example, I was part of the very ‘institutional environment’ that I was studying, which made it difficult to always maintain a critical distance from the research. Also, my own understandings were likely to some extent constrained by the very institutionalisation I was exploring. My key finding – that there is an institutionalisation of ideas – would also apply to me; like my participants, I at times found it difficult to think critically beyond existing understandings and consider alternatives.

### **4.3 Ethics Approval**

Given the topic of this project, which explores ethical practices in research, it is particularly important to acknowledge the process through which this project attained ethical approval. I submitted a Level Two ethics form to the University of Edinburgh’s School of Social and Political Studies’ Research Ethics Committee. This detailed how I would comply with the School’s ethical policies and

procedures, and was submitted, together with a copy of my Participant Information sheet and consent form (see Appendix VIII). On the form, I noted that the project entailed a risk for participants, in that my data could produce information about people and organisations who have behaved in ways deemed unethical, thereby potentially damaging their credibility. However, all documents used were in the public domain, and I stated on the form that care would be taken not to go beyond, them or to overly personalise, them, with the research focusing more on organisational than individual practices. Further, interviewees were offered the option of anonymity. I received approval from the Committee in April 2013, with it being acknowledged that all ethical issues arising from the research design had been addressed and that there were no other reasonably foreseeable ethical risks.

#### **4.4 Epistemological stance: Critical realism**

The philosophy of critical realism, most closely associated with the work of Roy Bhaskar (Bhaskar, 2008, Bhaskar, 2009), emerged from debates between the two epistemological poles of realism and social constructivism (see also Archer et al., 1998, Sayer, 2000, Fairclough et al., 2004). Critical realists accept that there is a world that exists independently of our perceptions and theories, with existing underlying structures and mechanisms. Yet, unlike realist thinkers, they believe that our understanding of reality is inevitably constructed from our own different perspectives of it; it is impossible to have any one, certain, objective knowledge of the world: 'Ontology must be distinguished from epistemology, and we must avoid the 'epistemic fallacy' of confusing the nature of reality with our knowledge of reality.' (Fairclough, 2005, p. 922) Thus, while critical realists do accept the existence of a 'real' world, independent of their perceptions, theories and constructions, they also believe that it is possible for there to be alternative valid accounts and interpretations of phenomena (Maxwell, 2012, Sayer, 2000). Bhaskar (2008) distinguishes between intransitive and transitive domains of knowledge. The intransitive encompasses physical processes or social phenomena: 'the intransitive objects of knowledge

are in general invariant to our knowledge of them; they are real things and structures, mechanisms and processes, events and possibilities of the world; and for the most part they are quite independent of us.' (Bhaskar, 2008, p. 22) The transitive domain includes theories and discourse as scientific resources (although as part of the social world, these too can be objects of study) (Sayer, 2000). By making this distinction, Bhaskar indicates that the empirical, 'real' world should be differentiated from our experience of it; this can be extended to the social world: there is a real social world, and there is also the knowledge that arises from investigations of it (Law and Urry, 2004). Thus, critical realism allows one to distinguish between the 'real', 'natural' world, which exists independently of our knowledge of it, and the social one, which is dependent upon human knowledge and is socially constructed.

In his writings on science, Bhaskar (2008) describes 'two sides of knowledge' (p. 21). In the natural sciences, he argues, there exist objective facts (the intransitive domain). Yet the production of knowledge is socially constructed, and thus those facts are subject to interpretation (the transitive realm). Bhaskar's epistemological philosophy of critical realism informs this research in several ways. It can help to explain how actors' perceptions and experiences can affect the ways in which interpretations of scientific (specifically, medical/health research) data are constructed: this is of central importance to the topic underpinning this study. For example, it has been shown that medical/health studies and data can be framed in journals in certain ways to produce particular results (see Chapter Two, Section 2.3.3). Further, and directly relevant to the primary research question (see Section 4.1), it allows us to recognise that, while interests are real and objective, actors' understandings of COIs and how they should be managed, which may be perceived as 'reality' (Berger and Luckmann, 1966), are in fact socially constructed. Thus, the philosophical paradigm of critical realism guided me in my exploration into the ways in which the subjectivities of those within the institutional environment of medical journal publishing affect their management of real interests.

In line with this critical realist epistemology, while this thesis assumes that research publications can only ever be *representations* of reality, it also assumes that particular approaches can, and do, get us closer to that reality than others. Accordingly, this thesis uses the term ‘bias’ to mean situations in which ‘systematic error’ has been introduced into the research and/or publication process ‘by selecting or encouraging one outcome or answer over others’ (Merriam-Webster.com, n.d.).

## **4.5 The role of theory**

While conducting my literature review, I found that COIs in medical research is a relatively under-theorised topic, and as such there was little to draw on in this regard. The more general literature on COIs and disclosure is discussed in Chapter Two (see Sections 2.2 and 2.5.1). While this did inform my interview questions, this PhD is very much an empirically-driven project, informed by the meta-theory of Critical Realism (as discussed in Section 4.4), with theories on institutionalism and deinstitutionalism emerging from my data and helping to explain my results (see Chapter Eight). The wording of my research questions (see Chapter One, Section 1.3) was consequently modified to include the term ‘institutional environment’ to reflect this theoretical perspective and provide a sense of cohesion across the thesis.

However, it is important to also acknowledge that certain wider theories informed my prior understanding of the topic and underpinned my initial research questions. My original supervisors at the University of Strathclyde were influenced by theories of Neomarxism. They introduced me to Herman and Chomsky’s propaganda model (1994); according to this, those in power use the media – i.e. ‘effective and powerful institutions’ (p. 306) – to manufacture the consent of society through the use of propaganda. This way of thinking underpinned my early understanding with regards to this research topic, and influenced my interview questions: medical journals can be used by powerful actors, such as the pharmaceutical industry, to further their interests. This can

be done, for example, through medicalisation or ‘disease-mongering’ (Moynihan and Cassels, 2005, Moynihan et al., 2002) – that is, creating diseases to match innocuous symptoms or non-medical problems – and then promoting medical solutions for them. This on-going underlying interest in the role of power in in COI management led me to explore, when examining my results, theories of regulatory capture to understand why existing processes to manage COIs do not work (e.g. Braithwaite, 1984, Abraham, 2008, Davis and Abraham, 2013), and also of agenda setting in order to investigate how particular ideas surrounding COIs are prioritised, while others are ignored or blocked (e.g. Sinclair, 1986, Birkland, 2011). Ultimately, however, I felt that theories of institutionalism and deinstitutionalism (e.g. Mahoney and Thelen, 2010, Scott, 2014, Peters, 2012, Hodgson, 2006, Jepperson, 1991, Tolbert and Zucker, 1996, Schmidt, 2008b, 2008a, 2010b, 2010c, 2010a) were more suited to helping me interrogate and interpret my data, and to answer research questions of how a narrow and fixed way of thinking about COIs has developed within the medical journal publishing industry. I consequently drew on these theories during the analysis and development of Chapter Eight.

#### **4.6 The data sample**

The data used in this research consisted of a combination of semi-structured interviews and COI policy/guidance documents, which were triangulated with each other. According to Denzin (1989), triangulation, a concept borrowed from surveying and navigation, can refer to the use of: several investigators to analyse data; more than one method of analysis of data; or, as in the case of this research, different types of data. Analysing more than one kind of data offers insights into the research problem at different levels, and thus provides a more comprehensive picture: it therefore arguably produces ‘better knowledge in the research’, as it increases its scope, depth and consistency (Flick, 2009, pp. 405, 445). In the case of this research, analysis of the documents allowed me to view how organisations within the medical journal publishing industry (and the individuals comprising those organisations) have constructed understandings of

COIs and their management, while the interview data offered a further insight into the subjective knowledge and experiences of those individual actors. Thus, through the triangulation of both documentary and interview data, this research offers an innovative qualitative study into how COIs are conceptualised within the institutional environment of medical journal publishing.

To protect my data, and in line with the UK Data Protection Act (1998), I kept my interview transcripts and coded data on password protected computers, while the consent forms were stored in a locked filing cabinet in my house. All of my data were backed up on a secure Cloud programme, 'Carbonite'.

#### ***4.6.1 Documentary data: conflicts of interest guidance and policies***

Prior (2008) writes that, traditionally, social researchers have viewed documents as static objects, which simply serve as containers of evidence (e.g. Scott, 1990). He argues, however, that they are not merely receptacles of information: they are also active agents and can therefore be considered as data in their own right, rather than just supporting other data; analysis needs to look at how realities are (re)produced through text (Atkinson and Coffey, 2004). Discourse arguably does not simply reflect social reality; it also plays a role in actively constructing it (ibid), and the function of written texts as active agents in this process should be considered. In the case of this research, the descriptions of COIs within the policies and guidance inform their conceptualisation by actors within medical journal publishing; these understandings in turn become recognised as being the reality. As such, from a critical realist perspective, I wanted to examine the various policies and guidance that the organisations within the medical journal publishing industry have developed in order to investigate how they conceptualise and shape understandings of COIs and their management.

As the industry of medical journal publishing is large, with an extensive number of policies and guidance available, I mainly followed a 'purposeful'

approach in my document sampling (Patton, 1990, pp. 169-86), selecting a manageable number of 'information-rich' cases from across the industry. Specifically, I followed the approach described by Patton (1990) as 'typical case sampling' (p. 173). The aim of this sampling method is to get data that is characteristic of the field as a whole. I sampled policies from the various different types of organisations involved in the medical journal publishing industry: journals, publishers, professional associations and companies from the manufacturing sector. In choosing my sample journals, I also employed the method of 'stratified purposeful sampling' (Patton, 1990, p. 174). This involves researchers choosing typical cases from different stratum in order to provide a picture of what is typical across various levels; in the case of this research, I used a sample of both well-resourced, high impact factor (IF) journals and journals that were selected due to their involvement in contentious cases, as outlined in Chapter Two, Section 2.4; this latter sample were generally smaller, less well-resourced publications. These sampling approaches allowed me to acquire a rich selection of documents from significant actors.

#### *4.6.1.1 Selecting the document sample*

With regards to my journal sample, I first picked a selection of well-resourced, high impact factor (IF) journals. A number of the editorial staff on these publications are also involved with the professional publishing associations, contributing to their work on publication ethics. It might therefore be expected that such journals would have more detailed COI policies. While it has long been acknowledged that the IF can be a somewhat crude measure (e.g. Seglen, 1997), a study by Ancker and Flanagin (2007) did find that journals with a higher IF were consistently more likely to have published COI policies, and that this dropped linearly with IF ranking; this finding has been supported by two other studies: Blum et al. (2008) and Weinfurt et al. (2008) (for more on these studies, see Chapter Two, Section 2.5.2); this measure therefore informed my sample design. I identified this sample by running a search on Thomson Reuter's Web of Knowledge for the top ten medical (general and internal) journals, measured



by IF. As discussed above, in order to develop a more diverse picture of the COI policies/guidance provided by journals that publish medical/health research, I followed a 'stratified purposeful sampling' approach and therefore also sampled the policies/guidance of a number of smaller journals that are known to have at some point been charged with engaging in practices that are, to varying degrees, considered ethically problematic. To select this sample, I used those journals that were referred to in Section 2.4 of Chapter Two. These are referred to in this thesis as 'contentious case' journals. As such, my overall journal sample consisted of rich, but not unusual, examples through which to explore the topic under investigation. This mixture enabled me to develop a sense of the range of guidance on publishing ethics that exists within the institutional environment of medical journal publishing. Tables 4.1 and 4.2 provide lists of the journals included in the sample. I searched each journal's website for their COI policies, and also tested their disclosure processes during submission to see if any further guidance was provided at this stage. Appendix I lists the guidance on COIs provided by each journal that was included in the sample, its format and specified target audience.

Table 4.1: Top 10 medicine (general and internal) journals, measured by Impact Factor (IF), 2012

<b>Journal</b>	<b>IF</b>	<b>Publisher</b>
<i>NEJM</i>	51.658	Massachusetts Medical Society
<i>The Lancet</i>	36.427	Elsevier
<i>JAMA</i>	29.978	AMA Publishing Group
<i>BMJ</i>	17.215	BMJ Group
<i>PLoS Medicine</i>	15.253	Public Library of Open Science
<i>Annals of Internal Medicine</i>	13.976	The American College of Physicians
<i>BMC Medicine</i>	6.679	Biomed Central (part of Springer)
<i>CMJA</i>	6.465	Canadian Medical Association
<i>JIM</i>	6.455	Wiley-Blackwell
<i>Mayo Clinic Proceedings</i>	5.790	Elsevier

Table 4.2: 'Contentious cases' journals (\*IF = Impact Factor 2012)

<b>Journal</b>	<b>Ethically Problematic Practice</b>	<b>IF*</b>	<b>Category</b>	<b>Publisher</b>
<i>JNCI</i>	Ghost-written articles on tobacco (Fields and Chapman, 2003)	14.161	Oncology	OUP
<i>JAACAP</i>	Published a ghost-written article on a key trial on the use of Paroxetine in adolescent depression, which misrepresented the data (Jureidini et al., 2008, McHenry, 2005, McHenry, 2010, McHenry and Jureidini, 2008)	6.970	Psychology, developmental; Psychiatry	Elsevier
<i>AJM</i>	Journals with a low print-run that are known to publish supplements (Flanagin et al., 1998)	5.812	Medicine (general and internal)	Elsevier
<i>JCP</i>	Ghost written letters on Paroxetine (McHenry, 2005, McHenry, 2010)	5.799	Psychology, clinical; Psychiatry	Physicians Postgraduate Press
<i>AJOG</i>	Journals with a low print-run that are known to publish supplements (Flanagin et al., 1998)	3.425	Obstetrics & gynecology	Elsevier
<i>AJC</i>	Journals with a low print-run that are known to publish supplements (Flanagin et al., 1998)	3.209	Cardiac & cardiovascular systems	Elsevier

<i>Risk Analysis</i>	Article which did not acknowledge funding from tobacco industry (McDaniel et al., 2005, Rampton and Stauber, 2002)	2.278	Public, environmental & occupational health; Social sciences, mathematical methods	Wiley-Blackwell
<i>Clinical Therapeutics</i>	Ghost written articles for Wyeth, by Excerpta Medica (Elliott, 2004)	2.230	Pharmacology & pharmacy	Elsevier
<i>IAOEH</i>	Article on Environmental Tobacco Smoke, published without consent of principal investigator and misconstruing data, (Chapman, 2005, Yano, 2005)	2.198	Public, environmental & occupational health	Springer
<i>Environmental Technology Letters</i>	Article which did not acknowledge funding from tobacco industry (Nielsen and Glantz, 2004)	1.606	Environmental sciences	Taylor & Francis
<i>Teratogenesis, Carcinogenesis &amp; Mutagenesis<sup>11</sup></i>	Peer-reviewed article which did not acknowledge funding from tobacco industry (Zeltner et al., 2000)	1.971	Oncology; Genetics & heredity; Toxicology	Wiley-Blackwell

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<sup>11</sup> Re-launched as *Birth Defects Research Part B: Developmental & Reproductive Toxicology* in 2003.

As I wanted to develop a picture of how the medical journal publishing industry as a whole conceptualises COIs, I needed to look at more than just the documents produced by the journals. I therefore also wanted to examine the sections on COIs in the guidance and policies of other relevant organisational actors, as identified in Chapter Three: publishers and professional associations. The professional associations, listed in Table 4.3 (together with the policies/guidance they provide), were identified through references and citations in the guidance and policies of the sample journals, the interviews and references to them in my literature review (Chapter Two). The websites of these professional associations were comprehensively searched for all guidance and policy information on COIs. In order to select a sample of publishers, I identified those commercial publishers responsible for the journals in my sample (see Table 4.4), and similarly thoroughly searched their websites for the information they provide regarding COIs. I did not include society publishers (such as the American Medical Association, which publishes *JAMA*) as their journal publishing efforts are limited, and it is likely that the policies of their journals would be closely reflective of them, so offer little new information (see Tables 4.1 and 4.2 for lists of journals and their publishers).

*Table 4.3: The professional associations' policies and guidance included in the sample*

<b>Professional Association</b>	<b>Guidance</b>
International Committee of Medical Journal Editors (ICMJE)	Uniform Requirement on Manuscripts - authorship and conflicts of interest (ICMJE, 2009) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (ICMJE, 2013) ICMJE Form for Disclosure of Potential Conflicts of Interest (ICMJE, n.d.)
Committee on Publication Ethics (COPE)	Code of Conduct and Best Practice Guidance for Journal Editors (COPE, 2011) COPE Ethical Guidance for Peer Reviewers (COPE, 2013) Principles of Transparency and Best Practice in Scholarly Publishing (COPE, 2014) Code of Conduct for Publishers (COPE, n.d.)
World Association of Medical Editors (WAME)	Guidance on Editorial Independence (WAME Editorial Policy Committee, 2009) Guidance on Conflicts of interest (WAME Editorial Policy and Publication Ethics Committees, 2009, WAME et al., 2013) Policy Statements on authorship and ghost-writing (WAME, 2005, WAME Editorial Policy Committee, 2007, WAME Editorial Policy Committee, 2005a) Guidance on Clinical Trial Registration (WAME Editorial Policy Committee, 2005b)
Council of Science Editors (CSE)	White Paper on Promoting Integrity in Scientific Journal Publications (CSE Editorial Policy Committee, 2012)

European Medical Writers Association (EMWA)	Guidance on role of medical writers in peer-reviewed publications (Jacobs and Wager, 2005)
American Medical Writers Association (AMWA)	Guidance on acknowledgements of medical writers (Hamilton and Royer, 2003, Mitrany et al., 2003)
International Society of Medical Publishing Professionals (ISMPP)	Good Publication Practice 2 Guidance (GPP2) (Graf et al., 2009) ISMPP Code of Ethics (ISMPP, n.d.)

Table 4.4: The publishers' policies/guidance

<b>Publisher</b>	<b>Guidance</b>	<b>Format and Audience</b>	<b>URL (accessed March 2015)</b>
Elsevier	'Conflict of Interest' (Elsevier, n.d.)	Online pdf fact sheet for authors and editors	<a href="http://www.elsevier.com/_data/assets/pdf_file/0007/163717/ETHICS_COI01a.pdf">http://www.elsevier.com/_data/assets/pdf_file/0007/163717/ETHICS_COI01a.pdf</a>
	'Policies and Ethics: Policies for Authors' (Elsevier, 2016b)	Online guidance for authors	<a href="https://www.elsevier.com/authors/journal-authors/policies-and-ethics">https://www.elsevier.com/authors/journal-authors/policies-and-ethics</a>
	'How to Conduct a Review' (Elsevier, 2016a)	Online guidance for reviewers	<a href="https://www.elsevier.com/reviewers/how-to-conduct-a-review">https://www.elsevier.com/reviewers/how-to-conduct-a-review</a>
	'Undisclosed Conflicts of Interest' (Elsevier, 2016c)	Online guidance for editors as part of the Publishing Ethics Resource Kit	<a href="https://www.elsevier.com/editors/publishing-ethics/perk/undisclosed-conflicts-of-interest">https://www.elsevier.com/editors/publishing-ethics/perk/undisclosed-conflicts-of-interest</a>
Oxford University Press	'Conflict of Interest' (Oxford University Press, 2014)	Online guidance for authors	<a href="http://www.oxfordjournals.org/en/help/faq/authors/conflicts-of-interest.html">http://www.oxfordjournals.org/en/help/faq/authors/conflicts-of-interest.html</a>



Springer Healthcare	'Publishing Ethics for journals: A guide for Editors-in-Chief, Associate Editors, and Managing Editors' (Springer, 2013)	Pdf guide book available online for editors	<a href="http://resource-cms.springer.com/springer-cms/rest/v1/content/4252/data/Publication_Ethics_Guide_for_Editors_from_Springer_27052013">http://resource-cms.springer.com/springer-cms/rest/v1/content/4252/data/Publication_Ethics_Guide_for_Editors_from_Springer_27052013</a>
	'Publication Ethics' (Springer, 2014)	Online guidance for authors	<a href="http://www.springer.com/authors/journal+authors/journal+authors+academy?SGWID=0-1726414-12-837825-0">http://www.springer.com/authors/journal+authors/journal+authors+academy?SGWID=0-1726414-12-837825-0</a>
Taylor & Francis	'Publishing Ethics': (Taylor & Francis, 2014)	Online guidance for authors	<a href="http://journalauthors.tandf.co.uk/preparation/ethics.asp">http://journalauthors.tandf.co.uk/preparation/ethics.asp</a>
Wiley	'Best Practice Guidance on Publication Ethics: A Publisher's Perspective' (Deakin et al., 2014)	Guide book available online for authors, editors and reviewers	<a href="http://media.wiley.com/assets/7324/10/Best-Practice-Guidance-on-Publishing-Ethics-2ed.pdf">http://media.wiley.com/assets/7324/10/Best-Practice-Guidance-on-Publishing-Ethics-2ed.pdf</a>

#### ***4.6.2 Semi-structured interviews***

COI policies and guidance play an important role in the conceptualisation of COIs in medical journal publishing: they not only reflect the ideas of those actors that created them, but they also inform other actors' understandings, and consequently play an active role in the construction of the reality surrounding COIs. They were thus an important inclusion in the data corpus. However, as shown in the introduction to this section, they cannot on their own produce a complete understanding of the field (Wolf, 2004, Atkinson and Coffey, 2004). Thus, as discussed above, I also conducted 48 semi-structured interviews with actors working within the institutional environment of medical journal publishing. While it has become a popular method, effective qualitative interviewing – that produces informative answers – is a difficult task (Fontanna and Frey, 1994), and although I had previously conducted research interviews as part of my professional work in the publishing industry, these were of a different kind to the type required for more formal research. Therefore, in preparation for conducting my fieldwork, I attended a two-day course, 'The Art of Qualitative Interviewing' at the University of Essex, which provided me with both theoretical and practical experience in the process of interviewing for social science research.

The interviews allowed me to acquire more in-depth, detailed data and to gain an insight into the subjective knowledge of those who produced the documents, as well as those who use them to inform their own understandings (Brinkmann, 2013, Kvale, 2006, Kvale, 1996). Humans are conversational beings, and it is through conversations that we primarily interact with one another. As such, interviews – which are essentially conversations with a structure and purpose – have, since the 1980s, become a key method of data collection used in the social sciences (Kvale, 1996, Kvale, 2006). They act as a central tool for gaining knowledge about people's personal and social lives, allowing researchers to see the world from their participants' perspectives and to develop theory from their knowledge (Flick, 2009, Brinkmann, 2013, Kvale,

1996). They therefore allow the researcher to develop a greater understanding of the field than an analysis of documents alone would do. As discussed in Section 4.4, I took a critical realist stance in my approach to this research, and while I held the position that interests are real and objective, I wanted to explore how the subjective experiences of those working within the medical journal publishing industry affect their interpretations of those interests, and how those understandings subsequently come to be seen as being the reality. By conducting 48 in-depth interviews, I was able to explore further the social worlds of those working within the institutional environment of medical journal publishing, and further insights into how different actors conceptualise COIs (Silverman, 2004).

#### *4.6.2.1 Selecting the interview sample*

Pilot studies can be used to try out and pre-test research methods (Baker, 1999), as well as to collect basic information about the topic (Gilbert, 2008). I conducted five pilot interviews fairly early on in the project: one medical writer<sup>12</sup> (who I met at an industry conference) and four ‘medical publishing critics’<sup>13</sup> (who have conducted research and published articles on topics related to this thesis). These enabled me to gain a greater insight into the field and issues affecting it than reading the literature on its own would have achieved. They therefore allowed me to refine my research topic and questions, as well as helping me to practice my interviewing technique. They taught me, for example, not to unnecessarily repeat ground already covered, or to ask leading questions (criticisms that were raised by a couple of pilot interviewees when I asked for feedback). The pilot interviews also gave me the opportunity to practice interviewing both in-person and online via Skype. The data gathered from these were not included in the final analysis, as they covered broad ground rather than specifically relating to the final research questions that developed; however, two

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<sup>12</sup> European Medical Writers Conference, Berlin, 10<sup>th</sup> – 14<sup>th</sup> May 2011.

<sup>13</sup> This interview category is explained on the following page.

of the pilot interviewees were available to be re-interviewed as part of the final interview sample.

Having developed my research topic, and improved my interview schedule and technique, I conducted 48 interviews in total, which were included in the analysis (see Table 4.6). I wanted to approach ‘information rich’ (Patton, 1990) individuals who would be able to provide deep and meaningful data, so as with the documents, I targeted a cross-section of those involved in medical/health journal publishing to produce data that were typical of the field. To select interviewees, I contacted individuals from the sample journals (see Tables 4.1 and 4.2): editors in chief, senior/executive editors, associate editors and managing editors (see Chapter Three, Section 3.2.2 for information on these roles). I also contacted individuals in senior positions at the publishers whose policy/guidance documents were in my sample, as well as representatives from the professional associations whose guidance I had included. In addition, I wanted to speak to researchers/authors who had experience of publishing articles in my sample journals, to explore their awareness of the issues under study. I also contacted medical writers who often play a part in the development of medical journal articles, and whose role has attracted controversy (see Section 3.2.6, Chapter Three). I attempted to make contact with representatives from pharmaceutical and tobacco companies who work on the publication/communication teams, but I received only a limited response from them. Finally, I held interviews with five people who have been involved broadly in researching the field of publishing ethics, particularly in relation to pharmaceutical- and tobacco-funded research, in order to gain insights from their expert knowledge and perspectives on the topic under study (these are termed ‘medical publishing critics’ in this thesis). It is worth noting that a number of the interviewees fitted multiple role categories: for example, many editors were also representatives of professional associations, editors were also authors, and so on. However, they are referred to in this thesis under the category for which they were selected for interview.

I created a tracking spreadsheet containing the role categories and the individuals within each that I had identified for inclusion. These people were then emailed with a request for an interview at a mutually convenient time and location, depending on where they were located (for example, at industry conferences that we were both attending, at their offices, or over the telephone or Skype). The majority of the interviewing process took place between March and July 2013. There was also a small snowball element (Patton, 1990), whereby I either asked for, or participants offered, suggestions of other key actors in the field whom I could also approach with a request for an interview. I found this useful as I was able to establish contact, through interviewees' introductions and recommendations, with other relevant individuals who may not have otherwise spoken to me (Sturgis, 2008).

As Table 4.6 shows, the response rate varied between the role groups. With regards to the journals, it was generally easier to get interviews with representatives from those in the high IF category than with those from the sample of 'contentious case' journals, which were smaller, speciality publications. One can only hypothesise as to why this might have been the case. Possibilities are that the former are generally more aware of, and interested in, the issues being researched, and are more confident in their policies. They may also have had more time, due to having greater resources, than their counterparts on smaller journals: most medical journals, other than those with a high IF, generally have a small staff with part-time editors who juggle the journal alongside other work commitments (this was an issue that came up frequently in interviews). Representatives of the 'contentious case' journals may also have been wary of the research, due to the fact that the majority of them had already been cited in the literature for their involvement in ethically questionable practices (see Chapter Two, Section 2.4).

My sample from smaller, speciality journals was therefore supplemented, via 'convenience sampling' (Bryman, 2008, Patton, 1990), with additional interviews conducted with individuals from a similar journal demographic,

identified via participant lists of conferences I attended (see Table 4.5 for a list of these conferences). Patton criticises 'convenience sampling' as being neither purposeful nor strategic. However, I felt that it was helpful as it did to some extent allow me to make up for the gap created by the limited response from the 'contentious case' journals, in terms of offering me further insight into the experiences, knowledge and understandings of editorial staff on smaller, less well-resourced journals (which are common in medical and health publishing), as compared to the bigger, higher IF, general medical journals (see Table 4.1). As well as allowing me to identify such additional interviewees, my attendance at industry conferences and workshops also enabled me to establish connections with individuals I had previously identified that I wanted to interview (for example, individuals whose journals were on the guideline list, medical writers and medical publishing critics).

To select authors, I targeted those who had published in my sample journals. I identified those first authors whose articles appeared on the journals' websites under lists of 'most read', 'most downloaded', or 'most viewed'. A large number either did not respond, or replied stating that they were too busy to take part, in which case I made my way down through the lists. Medical writers were identified either by establishing contact during attendance at industry conferences (such as those held by the European Medical Writers Association), or through introductions from mutual contacts. As mentioned above, representatives of professional associations simultaneously fulfilled additional roles (such as medical writers or editors), and were thus interviewed in both capacities. Medical publishing critics were generally well known in the field, and I approached them to establish contact at conferences (see Table 4.5), or emailed them to introduce myself.

I experienced some difficulties in recruiting interviewees from other areas of the medical journal publishing industry, such as participants from pharmaceutical and tobacco companies (those involved in the publication processes) and from publishing houses (publishers overseeing journals, and

those involved in publication policy development). I was persistent within reason (after my initial email request, I sent several weekly reminder emails), and I managed to conduct a few interviews with individuals from these areas (see Table 4.6). Yeager and Kram (1995) argue that a ‘bureaucratic “instinct” to protect against intrusion into potentially sensitive matters’ (p. 41) can lead to difficulties in accessing interviewees in elite organisations. That, together with the fact that the focus of my research is perhaps a sensitive area for these organisations, could have contributed to my difficulties. Indeed, one of the publishing houses that I interviewed insisted that the Head of Global Corporate Relations sit in on the (telephone) interview. Additionally, some busy individuals may simply not have felt it worth their time to speak to a PhD student. The project might also have benefitted from more interviews with representatives from such organisations. The difficulty in gaining interviews with individuals from these sectors probably steered the project more towards focusing on the conceptualisation of COIs from the perspective of those working on journals, rather than across the institutional environment as a whole, as I had originally hoped. However, this is not necessarily a weakness, as it provides a particular insight into the interpretations of COIs of the actors within this area.

*Table 4.5: Conferences attended by the researcher*

<b>Conference</b>	<b>Location</b>	<b>Date</b>
EMWA’s	Berlin, Germany	May 2011
PharmdOut	Washington D.C., U.S.A.	June 2011
Selling Sickness: People Before Profit	Washington D.C., U.S.A.	February 2013
COPE’s European seminar	London, U.K.	March 2013
CSE’s annual conference	Seattle, U.S.A.	May 2012
CSE’s annual conference	Montreal, Canada	May 2013
Research Integrity	Montreal, Canada	May 2013

*Table 4.6: The interview sample<sup>14</sup>*

<b>Role</b>	<b>Description</b>	<b>Number contacted</b>	<b>Number interviewed</b>
Editors in chief	Head of the journal; has final control over which articles are published.	17	6
Executive editors	Head up a child journal of a larger publication.	6	3
Senior editors	Manage a child journal of a larger publication.	3	5
Associate editors	Senior members of editorial boards, who are involved in the reviewing and decision process.	22	1
Managing editors	Oversee the journal's day-to-day editorial activities. They generally either work directly for the Editor-in-Chief or for the publisher.	16	8
Publishers	Work for the publishers of the journals. They may advise Editors on journal policies. Some employees of publishers may manage journals.	19	3
Medical writers	Employed by agencies, industry or freelance; create documents (including journal articles) on behalf of authors.	4	4
Authors	Named authors who have published articles in the sample journals included in the study.	57	9

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<sup>14</sup> While some interviewees occupied more than one role, the category under which they are listed here is the one for which they were selected for interview, and it was from the perspective of these positions that they were asked to primarily speak.



Pharmaceutical company representatives	From the companies' publication/communication teams.	3	1
Tobacco company representatives	From the companies' publication/communication/public relations teams.	3	1
Industry consultant	Consultants employed by commercial companies to conduct research and write articles	1	1
Medical publishing critics	Researchers who have been involved in investigating the field of publication ethics.	6	6
<b>TOTAL</b>		<b>145</b>	<b>48</b>

#### *4.6.2.2 Describing the interview process*

The interviews were semi-structured. These are more in-depth than structured interviews, and thus allow the researcher to get closer to social actors' meanings and interpretations (Gilbert, 2008). As such, they allow us to see how actors construct their social worlds through the language they use. Semi-structured interviews, however, provide the interviewer with greater control than those that are completely open-ended: the interviewer can use an interview guide to orient themselves, but has freedom of movement in allowing the interviewee to cover topics in a more natural fashion as the conversation develops, and in probing particular areas of interest (Hopf, 2004). It also provides interviewees with greater opportunity to expand and elaborate than a structured interview would (Aldridge, 1995). I developed an interview schedule based on my research questions and prior knowledge of the field (see Appendix II for an example). Under each topic, a primary question was asked, followed by a series of follow-up, probing questions. Whilst I ensured that all topics in the interview

schedule were covered, there was flexibility to the order in which the questions were asked, and I was able to delve into interesting responses further, asking additional questions that were not necessarily in the schedule. This also allowed interviewees the opportunity to offer further insights into the issues they felt were of particular importance (Bryman, 2008). The interviews ranged in length from around 40 to 120 minutes; the majority ranged from 45 to 60 minutes.

Gillham (2006) emphasises the importance of thorough preparation prior to carrying out interviews. On each occasion, I researched my participants to ensure my interview schedule, and the way that I approached them, reflected their particular backgrounds and experiences. The interview schedules I employed therefore varied slightly depending on the interviewees, although they broadly covered the same topics and questions. After the interviews, I made notes on any specific issues surrounding the interview (such as the setting, the manner of the interviewee and any interruptions that occurred, which formed part of my data), as well as on any new areas raised that warranted further investigation.

Participants were sent a Participant Information sheet (see Appendix VIII) with my initial emails: this provided them with information on the project, their role in it and what would happen to the data that they provided: as this is an ESRC-funded project, interviewees were offered the option of consenting to having anonymous copies of their interview transcript/notes archived in the UK Data Archive, as part of the ESRC's policy on data archiving and sharing (Economic and Social Research Council, 2010). This document also included a consent form, on which participants were given the choice to opt out of being recorded; they were given this option again at the start of the interviews, but all were happy for me to record them, which I did using a small, unobtrusive digital recorder. The form also offered interviewees the option to remain anonymous (again, this was double checked with participants at the start of interviews), and I received a variety of responses to this. Thus, in the final thesis, there is a mixture, with some interviewees named and some simply referred to by their

role (so that it is clear from which job perspective the interviewee is talking) and a unique number (to distinguish them from others in the same role). Some interviewees, who had originally agreed to be named, requested during the interview that certain comments be made anonymous, which I agreed to; I therefore subsequently ensured that any such comments were not attributed to anyone in my writing up of the analysis (but, where necessary, their role and a unique number were given). There were also a couple of instances where interviewees, who had agreed to be named, made comments which were useful but, I felt, if attributed to them, could damage their professional integrity. While researchers differ in their approaches to such situations (Wiles et al., 2008), I agreed with my supervisors that it would be fairer to my participants to make such comments anonymous in the results chapters (with a note of this in the text), especially as such changes would not affect the integrity of the data. At times, organisational actors needed to be named in order to provide a complete context. This was somewhat problematic, as doing so had the potential to in turn lead to 'accidental' identification of individuals (Wiles et al., 2008). To limit this likelihood in such instances, I took care to try to not overly personalise data, and information that emerged about individuals or organisations was anonymised where appropriate, so that the research focused instead on organisational practices.

Fourteen of the interviews were conducted face-to-face, mainly at conferences and, on a couple of occasions, at participants' offices. However, the majority took place over the telephone and Skype. There is discussion in the methodological literature about the strengths and weaknesses of conducting interviews in this way (e.g. Chapple, 1999, Irvine et al., 2012, Novick, 2008, Gillham, 2006, Sturges and Hanrahan, 2004, Mikecz, 2012, Stephens, 2007, Fielding and Thomas, 2008). Traditionally, methodological textbooks have advised against them, arguing, for example, that it is harder to build up a rapport with participants; that 'non-verbal' data such as body language and facial

expressions,<sup>15</sup> along with other contextual data, will be lost; and that data may be more easily distorted (Gillham, 2006). Mikecz (2012) described his experience of conducting both telephone and in-person interviews, acknowledging the cost advantages of telephone interviews (both time and money), but arguing that it is harder to develop trust in them, or to probe for more detailed answers. Sturges and Hanrahan, however, found from a study on face-to-face versus telephone semi-structured interviews that there were no significant differences in the data collected via each technique (2004).

Indeed, interviews over telephone/Skype can have benefits (Chapple, 1999, Stephens, 2007). For example, they can be useful when the respondents are geographically dispersed. While I focused on English language publications, medical/health journal publishing is a global business and my research therefore had an international reach, with a number of participants based overseas (primarily the U.S., with some in Australia), as well as in various locations around the U.K.. As such, it would have been impossible to interview them face-to-face. Further, generally my interviewees were extremely busy people, and telephone/Skype interviews offered them more flexibility as they could easily alter the date or time if they needed to without causing any problems, which may have increased their willingness to participate in the research. For example, one interviewee was able to squeeze in an interview with me while commuting home after a day at work. In terms of developing a rapport with such interviewees, I had met several of them previously at conferences and had thus already established a connection with them. Additionally, as Chapple (1999) argues, useful data can be obtained without a prior relationship, and even in cases where I had not previously met interviewees, I did not generally feel that this negatively impacted upon the interview. One exception, perhaps, was with the interviewee from a publishing house, referred to in Section 4.6.2.1, who had the Head of Global Corporate Relations from their company sit in on the call. I was therefore

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<sup>15</sup> Skype does allow users to see each other if they choose to use the video function; however, I generally left this decision up to the interviewees to choose whichever option would make them feel the most comfortable.

very conscious of the fact that the interview was being monitored; it is possible that if we had met in person, we would have been better able to develop a rapport and relax, although it is likely that the presence of this colleague would still have made me a little nervous. With regards to 'naturalness', in some ways I found it easier to keep the interview flowing naturally over the telephone or Skype (where video was not used), as I was able to check my interview schedule without disrupting the conversation and making the interviewee feel uncomfortable by reminding them that they were in an interview. However, due to an inability to use non-verbal methods of communication to get my meaning across, such as gestures, I did have to word my questions more carefully, and I improved at this as the interviews progressed.

There were some problems, with participants perhaps not taking the interviews as seriously as they might have done in a more formal face-to-face setting. Hermanowicz warns that: 'breakdowns and misunderstandings in communication easily arise simply by being apart. Consequently the ability to conduct a meaningful conversation is readily compromised' (2002, p. 497). Indeed, the experience cited above with an interviewee speaking to me during their commute home did entail problems: the participant was distracted as they said goodbye to colleagues and during their journey, and we got cut off on several occasions. However, this can be weighed up against the difficulties I faced with some of the in-person interviews that were, by necessity, often held in noisy places such as hotel reception lobbies, with resulting distractions and background noise. When trying to interview busy individuals, it can be difficult to get the optimal situation; in my experience, by being flexible in my approach with regards to time, location and format, I was more likely to be successful in gaining access to such interviewees.

Some researchers have argued that interviews with 'elites' can be problematic, with the interviewee exerting power over the interviewer (Mikecz, 2012). Not all of my interviewees were in such positions of power. However, I did experience one clear example of a powerful interviewee (who could be

classified as an 'elite') using their position to try and exert some control over my research. This involved a well-known medical doctor and editor-in-chief of a top biomedical journal who agreed to be interviewed by me, and we arranged a time. Yet when we met, the individual refused to have a formal interview, and instead talked to me in public at a conference, immediately after a plenary talk they had given, with other attendees listening, who viewed the individual as an authority in the field. We were therefore very much in an environment in which the interviewee was more powerful than me, rather than in a neutral space. The interviewee appeared wary of my research focus, insisted on looking at my interview schedule, and dismissed it by stating that it was impossible to conduct such research using qualitative methods. After the brief conversation that followed, I agreed that I would write up my notes (as I had been unable to record the meeting) and email these to them for their approval. After ignoring my email for several weeks, I received a very abrupt response stating that the person wished to 'withdraw from the research'. This unpleasant experience, between a PhD student and a senior medical doctor running a leading medical journal left me feeling temporarily disempowered, and demonstrates clearly the ways in which power can be exploited by the interviewee over the interviewer. In all the other interviews, I did not feel that the participants attempted to use their positions to intimidate me in any way, no matter how significant they were in their field.

#### *4.6.2.3 Transcribing the interviews*

Considering the number and length of the interviews, transcription was extremely time-consuming, but doing it myself did enable me to get to know my data well and begin to identify themes for the analysis (see Section 4.7). I experimented with voice recognition software to see if I could speed up the transcription process, but aside from technical difficulties (which resulted in it being more time-consuming than simply typing), I found that I did not engage with the data as much as when I was typing it. I therefore quickly reverted to the more traditional technique. I considered using a professional transcriber to

speed up the operation; however, through doing it myself, I was able to immerse myself in the data. Further, as the creation of transcripts is a theory-laden process – one of interpretation or ‘translation’ (Hermanowicz, 2002, p. 497) – with the transcriber deciding what to include and what to leave out (Gillham, 2006), it is arguably preferable for the researcher, who developed the project questions and conducted the interviews, to produce their own transcripts where possible. While the interviews are constructions of interviewees’ social worlds, the transcripts are themselves selective constructions reflecting the researcher’s theoretical goals. Using a professional transcriber risks a third-party’s interpretative and theoretical lens affecting the process (Tilley, 2003). However, after having conducted the majority of my interviews, and subsequent to their transcription, I managed to establish contact with two further individuals who agreed to be interviewed. As I had by then begun the analytical work, and time was of the essence, I paid a professional to transcribe them using my ESRC funding, describing the level of transcription I required. I understandably did not, however, feel quite as comfortable with those transcripts as I did with the ones I had done myself. To alleviate this, I listened to the recordings again and read over the the transcripts several times, ensuring that they were accurate. The transcriber was required to sign a confidentiality form.

While interviews are constructions of interviewees’ social worlds, the transcripts are themselves selective constructions reflecting the researcher’s theoretical goals (Ochs, 1979). Keeping this in mind, I decided to transcribe the interviews myself in their entirety, as accurately as possible (at times background noise and feedback made it impossible to capture every word), using the software ‘Express Scribe’. This meant that all of the conversation would be available during the analysis stage and I would not lose any context. I excluded non-lexical vocables or utterances, which were not relevant: Kowal and O’Connell (2004) advise only transcribing those features of the interview that will potentially be analysed to lessen the potential for confusion; since I was not planning on conducting detailed conversation or discourse analysis, I felt it was unnecessary to go into more detail, and instead followed a process of

‘denaturalised transcription’, which focuses more on the informational content than speech patterns (Oliver et al., 2005). Indeed, Cook (1990) has argued that filling transcripts with columns and mathematical symbols can be more to do with a researcher’s attempts to *appear* to be scientific, rather than actually being scientifically rigorous. The purpose of the level of detail I included in the transcripts was to capture as much of the context as possible and to ensure that, when I went on to analyse the transcripts, I did not misconstrue what was said.

Some researchers recommend sharing interview transcripts with interviewees (Herzog, 1995), arguing that doing so allows participants to check the accuracy of the transcript, correct errors and provide clarification if needed. However, a study by Hagens et al. (2009) found that providing transcripts to interviewees entails risks, such as bias being introduced by inconsistent data sources (if only some transcripts are checked, they may contain more thoughtful and time-considered responses than those that are not), or valuable data being lost if interviewees choose to remove it, and yet they found there to be no evidence of improved accuracy of transcripts. I therefore decided not to provide interviewees with copies of their interview transcripts.

## **4.7 The analysis**

### ***4.7.1 The analytical approach***

Thematic analysis is a flexible method that can be conducted in a number of different ways (Bryman, 2008), and allows the researcher to identify, analyse and describe patterns in data (Braun and Clarke, 2006). This has led to criticisms that it lacks rigour. However, detailed suggestions have been developed within the social science research literature on ways in which it can be applied, which proponents argue should ensure thoroughness of practice. Bryman suggests that one general strategy that can be used is the ‘Framework approach’, originally designed for Applied Policy Research (Ritchie and Spencer, 1994): ‘a matrix based method for ordering and synthesising data’ (Bryman, 2008, p. 554).



Guest et al. (2012), while acknowledging that applied thematic analysis can encompass a range of analytic techniques, also provide a detailed discussion of the process that can be taken, as does (Boyatzis, 1998). Braun and Clark (2006) offer clear guidance, intended to ensure it is conducted rigorously, emphasising the importance of being clear and explicit about the approach taken, and the need for researcher reflexivity, to ensure the process is fully transparent. Attractions of using thematic analysis include the fact that it is not tied to any one epistemological or theoretical approach, as other methods such as grounded theory (Glaser and Strauss, 1967) are, but rather can be applied across a range of them. It also allows themes to be derived both deductively and inductively (or both) (Braun and Clarke, 2006). The approach I adopted drew primarily upon Braun and Clark's (2006) and Ritchie and Spencer's (1994) guidance.

Themes (codes) can arise both *a priori*/deductively (from an investigator's prior theoretical understanding of the topic being studied) and inductively (from the data itself). The former can emerge from characteristics of the phenomenon, topics identified in a literature review, common sense constructs, and researchers' own values, experiences and the theoretical framework within which they work. Inductive themes emerge from empirical data (Ryan and Bernard, 2003). Alternatively, themes can emerge through a mixture of the two approaches – abductively – which allows theories about the social world of those under study to be iteratively formed through the analysis (Blaikie, 2009).

#### **4.7.2 The analytical process**

Patton (1990) argues that the analytical process begins with the collection of data, and while I was conducting interviews and collecting documents, I noted down ideas that emerged (Burnard, 1991). When it came to coding the data, I followed an abductive approach (Blaikie, 2009), with the aim of developing theory from the data, while also accepting that some of my own theoretical pre-assumptions would affect my interpretation of it and my selection of themes

(Schmidt, 2004). The abductive research strategy has as its starting point the social world of the actors being investigated: how they construct their reality, and conceptualise and give meaning to their social world (Blaikie, 2009). This approach fitted my research questions, which wanted to explore how actors working within the institutional environment of medical journal publishing conceptualise and construct realities around COIs and their management. A difficulty noted by Burnard (1991) is that this approach assumes that comments made by one interviewee can be compared with those of another – that their worldviews can be linked. While Burnard does not propose a solution for this, he recommends keeping it in mind as an intrinsic problem in this sort of analytical approach. Ritchie and Spencer's 'Framework approach' (1994) advises initial familiarisation with the data, as do Burnard (1991) and Braun and Clark (2006). This allows us to enter the life world of the respondents. As I had conducted the interviews and transcribed all but two, I was already fairly conversant in my data, but I did re-read the transcripts several times to ensure I was fully at ease with them. I also read over the sample policy documents. While I already had ideas of codes, based on my research questions and thoughts that had emerged during data collection, this process allowed further themes to emerge from the data (Lapadat, 2010). Further, as I had a large corpus of data, it allowed me to remove sections that I felt were not of relevance to my research questions. For example, journals' 'Instructions for Authors' typically contain information on a wide range of matters beyond COI, such as manuscript preparation, and interviewees sometimes went off on unrelated tangents (for example, on one telephone interview, my interviewee got distracted by their partner gardening and proceeded to briefly tell me about it before I got them back on topic!). Removing these made the analytical task more manageable.

I began with the process of 'open coding' (Berg and Lune, 2014), that is, freely generating codes to develop my thematic framework. For my interviews, I created an initial codebook, derived from my research questions and interview schedule, as well as relevant areas that had caught my attention during the transcription process and subsequent re-readings of them. These were in turn

informed by my knowledge of the field. I refined these key themes (along with sub-themes) as the coding progressed, depending on their relevance to the topic: some were removed, some amalgamated with others, while other new ones were added. This of course meant that I had to keep a list of when new themes were generated, and once I had been through all of the transcripts, I went back over them in order to ensure that new themes were captured and coded where applicable. The resulting final key themes are summarised in Table 4.7.

A separate set of key themes was also developed to code my sample documents. The aim of the analysis of this dataset was to discover the ways in which such documents structure ideas surrounding COIs and their management. Hacking uses 'idea' as shorthand for items that are socially constructed (Hacking, 1999), and I use the term in this thesis in relation to the social construction of understandings regarding COIs which come to be understood by actors within medical journal publishing as an external reality. The codes were developed along the same lines as those for the interview data, being based on my research questions and thoughts that had emerged during data collection; a list of key codes is provided in Table 4.8. Tables on particular topics of interest in the documents were then developed within which I put relevant coded text, such as: which actor group was required to disclose conflicts; when and how should actors disclose; and what were they required to disclose. While I primarily used a CAQDAS (Computer-Aided Qualitative Data Analysis Software) (discussed below) to organise my data, I found that these tables allowed the relevant data pertaining to particular questions to be presented clearly in one place when performing the analysis, enabling me to assess whether the impressions I had formed while coding were supported by the data.

As discussed above, as the analysis progressed, more parent themes/codes developed from the data, together with new child themes/-codes, and each previously coded data item had to be returned to in order to check for coverage of the new codes. Once a complete coding book had been developed, the codes were mapped onto the results chapters in preparation for the analysis.

Due to the large volume of data, I decided to use a CAQDAS, specifically NVivo, to assist me in the tasks of organising, retrieving, comparing and linking them (Patton, 1990). As such, all of the data (both interviews and documents) were imported into NVivo for qualitative analysis and the codes were added to the project there. This allowed me to easily locate coded themes and compare sections of data. I had attended a two-day course on using NVivo, run by the University of Surrey, which helped me in setting up the project initially, as well as teaching me how to manage my data and about the software's different functions. I was also guided by Bazeley and Jackson's manual on NVivo (2013). While NVivo can be used to assist in more complex analytical tasks, both qualitative and quantitative, for this project it was used in a relatively basic manner, such as coding the data and searching for particular themes. It also allowed me to add memos to the data, and to do slightly more complex tasks, such as view particular codes by the job role of interviewees. I was further able to assess the frequency of particular themes; these numbers are at times referred to in the analysis to give readers an insight into their relevance.

*Table 4.7 A summary of key themes used to code interviews*

<b>Key themes in interviews</b>	<b>Key sub-themes in interviews</b>
<i>Authorship</i>	<i>Authorship criteria</i> <i>Ghost authors</i> <i>Medical writers</i> <i>Contributors</i> <i>How authorship relates to COIs</i>
<i>Conflicts of interest</i>	<i>Development of COI policies</i> <i>Who can potentially be conflicted?</i> <i>What is a COI?</i> <i>Types of interest that can lead to conflicts</i> <i>How can undisclosed conflicts be discovered?</i> <i>How can COIs be managed</i>

<i>Bias</i>	<i>Publication bias</i> <i>How it's hidden</i> <i>How to identify it</i> <i>Types of bias</i>
<i>Disclosure</i>	<i>Purpose of disclosure</i> <i>Who should disclose?</i> <i>How should they disclose?</i> <i>What should be disclose?</i> <i>The evaluation of disclosures</i> <i>Methods of and formats for disclosure</i> <i>Strengths and weaknesses</i> <i>Standardisation of/ variations in disclosure</i> <i>How to respond to non-compliance</i>
<i>Guidance and policies</i>	<i>Purposes of guidance/policies</i> <i>Awareness of and adherence to guidance/policies</i> <i>Reference to particular guidance/policies</i> <i>Criticisms of guidance/policies</i> <i>Strengths of guidance/policies</i>
<i>Industry</i>	<i>Pharmaceutical industry-funded research</i> <i>Tobacco industry-funded research</i> <i>Comparing pharmaceutical with tobacco industry-funded research</i>
<i>Other processes</i>	<i>Clinical Trial Registration</i> <i>Clinical Trial Protocols</i> <i>Reporting guidance</i> <i>Peer review</i> <i>Journal Oversight Committees</i> <i>Non-publication policies</i>
<i>Resources</i>	<i>Availability and constraints</i>
<i>Suggestions of other ways to</i>	<i>Central database</i> <i>Change publishing model</i>

<i>manage COIs</i>	<i>Change research model</i> <i>Open Access data</i> <i>Contributorship model</i> <i>Refuse to publish</i>
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*Table 4.8 A summary of parent codes used for policy and guideline documents*

<b>Key themes in policies and guidance</b>
What are conflicts of interest?
Conflicts of interest - types of interest that can lead to conflicts
Disclosure – who and how?
Disclosure – type of article
Data access
Editorial independence
Medical writers and ghost writers
How to respond to non-compliance
ORCID
Publication policy
Responsibility for handling cases of misconduct
Supplements policy
Clinical Trial Registration
Clinical Trial Protocols
Reporting guidance

## **4.8 Writing up the research**

I initially looked at examples of PhD theses to explore different formats and structures. Gilbert (2008) advises writing from as early as possible in a project, and to continue doing so over its course. From the beginning, I made notes on the relevant research literature that I looked at, and began to write drafts of my literature review (Chapter Two) in the first year of my PhD: this helped to

immerse me in the field of publication ethics and become acquainted with the various issues and debates it entails. I then moved on, after attending a module on 'Research Design' at the University of Edinburgh, to working on early drafts of sections of this methodology chapter; this allowed me to establish my epistemological stance and to familiarise myself with different methods of data collection and analysis. Once the analysis had been conducted, I commenced the process of writing up the results, that is, translating my data into an appropriate form for my readers (Matt, 2004), and finally my discussion. When these were completed, I went back and revised my literature review; as the project had grown, altered and developed to focus specifically on COIs and their management, I wanted to ensure that I had looked at and discussed all of the writing relevant to the topic. I was also able to complete this methodology chapter to include all the details of my approach to the project.

The relationship of the researcher to the writing deserves some consideration here. Written text produces a fixed representation of reality and an objectification of meaning (Matt, 2004), but it is not possible for it to be value-free: this is the case of both the interview transcripts, documents and the final thesis. For example, in one transcript I made a note of an 'awkward silence'; this was only my interpretation of the pause in the conversation, but it would affect my analysis. Given my epistemological stance (see Section 4.4), and interest in exploring how particular ideas regarding COIs are constructed and understood to be reality through their presentation in policies and guidance, it is particularly important that it is noted that what I present as the 'reality' in my results and discussion chapters is in fact only my interpretation of the research topic and data, it is not an objective fact: writing cannot be truly detached and neutral (Gilbert, 2008). Through applying my own voice and theoretical perspectives to the narrative, and choosing which data (such as illustrative quotes) to present, and which to keep back – referred to as 'selective plausibilization' by Flick (2009, p. 384) – I am in turn socially constructing a version of reality for my readers.

That said, my task in writing my results and discussion chapters was to present as reliable a portrayal of my data as I could. Flick discusses several ways that can help with this, such as procedural reliability and validity (2009, p. 386). I thus tried to gather and analyse my data in as reliable and valid a fashion as possible. Training in data acquisition and analysis can help with this (ibid): to equip myself with the necessary tools, along with attending the course on interviewing techniques, referred to in Section 4.6.2, I also completed the module 'Analysing Qualitative Data' in the School of Social and Political Science at the University of Edinburgh, and attended a two-week course in 2012, 'Qualitative Text Analysis', at the University of Essex's Summer School. Ensuring that my data was gathered and analysed in a robust manner increases its general reliability. I have also attempted to be as clear and reflexive as possible in this chapter of the ways in which I conducted my research, providing an account of my epistemological stance, and how and why I sampled and analysed my data. Further, where possible, my data will be made available to the ESRC after the project has completed, in line with their data access policy (Economic and Social Research Council, 2010), and therefore be available for researchers to analyse in the future.

#### **4.9 Concluding summary**

This chapter has presented the research strategy and paradigm through which this project was approached, and outlined the methods employed in the data collection and analytical processes. It has shown how I triangulated my data collection, using both documents and interviews, in order to answer the research questions posed in Chapter One. Previous studies on this topic (see Chapter Two, Section 2.5.2) have been primarily quantitative and used only one type of data source. The qualitative approach to these questions, utilising data from actors across the medical journal publishing industry, as has been outlined in this chapter, was innovative. It therefore provides an original insight into the topic of how COIs are conceptualised within the institutional environment of medical journal publishing. Along with offering an overview of the approach to data



collection and analysis that I used, this chapter has also provided reflections upon these methods. It has discussed some of the strengths and weaknesses relating to the epistemological stance of critical realism that I have taken. Transparently presenting the methodological processes of this research here enables the reader to proceed to review the results and discussion chapters with an understanding of how the material presented there emerged.

## **CHAPTER FIVE: RESULTS**

### **How do Actors Conceptualise Conflicts of Interest and Bias in Medical Journals?**

#### **5.1 Introduction to the chapter**

Chapter Four mapped the institutional environment of medical journal publishing, both in terms of individual agents and organisational actors. This chapter explores how this institutional environment understands COIs, both in terms of what it considers to be relevant COIs, and which actors it presents as potentially having conflicts that require management. It examines these constructions, both by individual agents (through my interview data) and by organisational actors (through my sample policies and guidance produced by publishing houses, journals and professional associations). In doing so, it allows readers to develop an understanding of how the medical journal publishing has constructed the topic of COI, with particular elements of the debate prioritised over others.

The chapter begins, in Section 5.2, by examining how particular actor groups are construed as having potential conflicts that are particularly problematic and require regulation, while others are absent from the debate and thus generally remain beyond the remit of existing regulatory approaches. It continues, in Sections 5.3 and 5.4, by looking at different types of interests – personal financial, funding and non-financial – and examines how specific relationships are portrayed as being especially challenging, and therefore necessitate management, while others are given less consideration and therefore, again, often escape regulation. The chapter concludes, in Section 5.5, by summarising the key findings and highlighting those that will be drawn upon further in Chapters Six and Seven.

## **5.2 Actor groups whose potential conflicts require management**

There is a diverse range of actors working in medical journal publishing who may have potential COIs that could affect the content of peer-reviewed medical journals. Chapter Two showed how the research literature has explored various aspects of COIs in medical research and publishing, and touched on several categories of actors whose conflicts may affect the journal literature (e.g. Young, 2009, Resnik, 2000, Resnik and Shamoo, 2002, Angell, 2000, Moses and Martin, 2001, Ngai et al., 2005, Lexchin and Light, 2006, Marcovitch, 2010). I analysed my data (both interviews and policy/guideline documents) in order to further identify which groups of actors are focused on in relation to COIs within the institutional environment of medical journal publishing, and consequently which are not.

### ***5.2.1 Potentially conflicted actor groups according to the guidance***

The actors whose potential COIs are discussed in the professional associations' guidance and policies are shown in Table 5.1. According to these documents, the main actors who are most widely seen as potentially having COIs are authors, followed by reviewers and journal editors. None mention specifically the types of conflicts that journal owners can face. Only EMWA, AMWA and ISMPP, which specifically represent medical writing professionals, refer to the need to disclose the funding of this group of actors. Given the controversy that has surrounded the use of medical writers in producing medical publications when they are undisclosed (a practice termed as 'ghost-writing'; see Chapter Two, Section 2.4), one might have expected that potential conflicts relating to this group would be discussed in more detail within the policies and guidance of the professional associations representing the medical publishing industry.

*Table 5.1 References in the sample professional associations policy/guidance to actor groups' COIs (shaded boxes represent no reference to an actor group)*

<b>Professional Association</b>	<b>Target Audience</b>	<b>Authors</b>	<b>Reviewers</b>	<b>Editors</b>	<b>Medical Writers</b>	<b>Journal Owners</b>
AMWA (Hamilton and Royer, 2003, Mitrany et al., 2003)	Medical Writers				✓	
COPE (COPE, 2011, 2014, n.d., 2013)	Editors Publishers	✓	✓	✓		
CSE (CSE Editorial Policy Committee, 2012)	Editors Publishers	✓	✓	✓		
EMWA (European Medical Writers Association, 2015b, Jacobs and Wager, 2005)	Medical Writers				✓	
ICMJE (ICMJE, 2009, 1985, 2014a, 2014c, 2013, n.d., 2015a)	Authors Journal Editors	✓	✓	✓		

ISMPP (Graf et al., 2009, ISMPP, n.d.)	Medical publication professionals	✓			✓	
WAME (WAME Editorial Policy and Publication Ethics Committees, 2009, 2007, 2005a, 2009, 2005b)	• Journal Editors	✓	✓	✓		
<b>TOTAL</b>		<b>5</b>	<b>4</b>	<b>4</b>	<b>3</b>	<b>0</b>

The guidance and policies provided on the websites of my sample publishers appear to be mainly aimed at authors, editors and reviewers. I analysed them to see which actors they discuss in relation to COIs (see Table 5.2). Three of the five refer explicitly to the potential COIs of authors, reviewers and editors, while two only mention authors' and reviewers' COIs. None of the publishers mention any other actor groups who might be conflicted, such as medical writers. It is also interesting to note that two publishers (Springer and Taylor & Francis) do not discuss editors' COIs, nor offer them advice on how to manage them.

*Table 5.2 Reference to actors' COIs in the sample publishers' guidance*  
(shaded boxes represent no reference to an actor group)

<b>Publisher</b>	<b>Authors</b>	<b>Reviewers</b>	<b>Editors</b>
Elsevier	✓	✓	✓
Oxford University Press	✓	✓	✓
Springer	✓	✓	
Taylor & Francis	✓	✓	
Wiley	✓	✓	✓
<b>TOTAL</b>	5	5	3

Policies and guidance developed by journals are primarily aimed at authors and peer reviewers; they also serve to inform the journals' readership of its requirements. The development of these may be informed by the guidance produced by professional publishing associations (such as ICMJE, COPE, CSE and WAME) and those of their publishers. Table 5.3 lists the journals included in my sample, together with which groups of actors they each refer to in relation to COIs.

Table 5.3 Reference to actors' COIs in sample journals' guidance (High IF journals are those marked with an asterisk; shaded boxes represent no reference to an actor group)

Journal	High IF or Contentious Cases	Author	Reviewer	Editor	Contributor (Other)	Medical Writer	Employer
<i>NEJM</i> *	HIF	✓	✓	✓			
<i>The Lancet</i> *	HIF	✓				✓	
<i>JAMA</i> *	HIF	✓	✓				✓
<i>BMJ</i> *	HIF	✓	✓	✓			
<i>PLoS Medicine</i> *	HIF	✓	✓	✓			✓
<i>Annals</i> *	HIF	✓	✓	✓	✓	✓	
<i>BMC Medicine</i> *	HIF	✓	✓	✓		✓	
<i>CMAJ</i> *	HIF	✓	✓	✓	✓		
<i>JIM</i> *	HIF	✓	✓	✓			
<i>Mayo Clinic Proceedings</i> *	HIF	✓	✓				
<i>AJC</i>	CC	✓					
<i>AJM</i>	CC	✓	✓	✓			
<i>AJOG</i>	CC	✓	✓	✓		✓	

<i>Birth Defects</i>	CC	✓					
<i>Clinical Therapeutics</i>	CC	✓					
<i>Environmental Technology</i>	CC	✓					✓
<i>IAOEH</i>	CC	✓	✓				
<i>JAACAP</i>	CC	✓	✓				
<i>JCP</i>	CC	✓	✓		✓	✓	
<i>JNCI</i>	CC	✓					
<i>Risk Analysis</i>	CC	✓					✓
<b>TOTAL</b>	<b>21</b>	<b>21</b>	<b>14</b>	<b>9</b>	<b>3</b>	<b>5</b>	<b>4</b>



This table draws on the policies and guidance publicly available on the journals' websites. Authors' COIs are referred to by all of the journals, both from the high IF and the 'contentious cases' samples. However, the picture is far more mixed with respect to the attention given to other actor groups. Despite the discussion of reviewers' and editors' potential conflicts in the guidance of the professional associations aimed at editors (COPE, CSE, ICMJE and WAME), reference to them in the journals' policies is more limited. Reviewers' potential COIs are mentioned by two thirds of the sample journals (14 out of 21, nine of which were from the high IF sample), and under half (nine) discuss editors' potential COIs (seven of which are from the high IF sample). There is also no mention, in the journal guidance publicly available, of how the potential COIs of journal owners are managed by any of the journals in the information they provide online. This is despite the fact that there have been several cases of editors in chief on high IF journals being fired by their owners (see Section 2.3.1.2, Chapter Two), and the CSE advising that 'The journal should institute procedures that guard against potential conflicts involving the editor or the journal owner' (CSE Editorial Policy Committee, 2012, p. 43) (see Chapter Seven, Section 7.2.2.3 for more on the management of COIs between editors and journal owners). This lack of guidance was mirrored in the limited discussion by interviewees on owners' COIs (see Section 5.4.2 of this chapter).

Also noticeably absent from most of the journals' policies/guidance (as well as those of the publishers, and the professional associations representing publishers) is discussion of contributors' – including medical writers – potential COIs. Despite debate in the research literature over their involvement in articles, there is limited information regarding their potential conflicts in the sample documents, perhaps because, as was suggested in interviews, they generally do not qualify for authorship (see Section 5.2.2 for more on this). Only five of my sample journals (*The Lancet*, *BMC Medicine*, *Annals*, *AJOG* and *JCP*) make specific reference to medical writers and their potential COIs. The journals in my 'contentious cases' sample that were included due to controversies over their use of medical writers – *JNCI*, *JCP*, *Clinical Therapeutics* and *Environmental*

*Technology Letters* – do not do so. Contributors are also rarely mentioned, with only three journals (*Annals*, *CMAJ* and *JCP*) referring to the need for individuals considered to be ‘contributors’ rather than ‘authors’ to disclose COIs in their guidance. Although a number of journals do discuss who should be mentioned in the acknowledgements of articles, the majority do not specifically suggest that the funding or employment of these individuals, and any other potential conflicts, should be disclosed.

### ***5.2.2 Potentially conflicted actors according to interviewees***

In addition to analysing the policy and guideline documents, I also asked interviewees who they felt may potentially have COIs that could affect the content of medical/health journals and should be disclosed. In response to this question, along with analysing the responses throughout the interviews, I was able to form a list of the groups of actors whom interviewees identified as potentially having COIs; this is summarised in Table 5.4. The interviewees are grouped according to their role<sup>16</sup> and are listed on the far left column, with the total number in each role category included in brackets. The top row of the table lists all of the actor groups that the interviewees suggested could have COIs that could have an effect on the content of journals. The number of the interviewees within each role category that referred to each potentially conflicted actor group is then shown within the table.

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<sup>16</sup> There was some overlap across roles, with interviewees fulfilling more than one; however, they are referred to in this thesis with regards to the capacity they were interviewed in.

Table 5.4 References to actor groups' COIs in interviews (shaded boxes represent no reference to an actor group)

		Potentially conflicted actor groups referred to by interviewees						
		Author	Reviewer	Journal Editor	Contributor	Medical Writer	Statistician	Owner (Society or Publisher)
Interviewees (categorised by role)	Associate editor (1)	1	0	0	0	0	0	0
	Author (9)	9	3	3	0	0	1	0
	Editor in chief (6)	6	3	3	1	0	0	1
	Executive editor (3)	3	0	2	0	2	0	1
	Manufacturing company representative (2)	2	0	0	0	0	0	0
	Managing editor (8)	8	6	7	1	1	0	1
	Medical writer (4)	4	3	2	0	1	1	1
	Publisher (3)	3	2	2	0	0	0	1
	Medical publishing critic (6)	6	1	4	0	1	0	0
	Senior editor (5)	5	3	3	0	2	0	0

	Industry consultant (1)	1	0	0	0	0	0	0
	<b>TOTAL (48)</b>	<b>48</b>	<b>21</b>	<b>26</b>	<b>2</b>	<b>7</b>	<b>2</b>	<b>5</b>

My analysis of the publishing guidance and policies indicates that there is a general consensus within the institutional environment of medical/health journal publishing that authors may have COIs that could impact on the content of medical journals, and this was supported by the interviewees. Likewise, this table shows that, mirroring the sample guidance and policies, interviewees' discussion of actor groups, beyond authors, was limited in relation to COIs. After authors, the COIs of journal editors, as an actor group, were the most frequently talked about, though as with the guidance, the focus of the interviews remained on authors. Discussion of reviewers' COIs were the next most discussed. There was limited talk of the COIs of journal owners, including by journal editorial staff. The two company representatives interviewed did not discuss the potential COIs of any groups of actors other than authors. While their focus may not be on the publishing processes – and as such it is unsurprising that they did not mention, for example, the potential COIs of reviewers – it is interesting that they did not talk about the potential COIs that journals and their owners may face with regards to supplements, reprints and advertising paid for by their companies (see Section 5.4.1 and 5.4.2 of this chapter for more on this). This is despite the fact that this has been a topic of concern (see Section 2.3.1.2 of Chapter Two). Only Thomas Lang (medical writer), a publisher (P1), an executive editor (Annette Flanagan, *JAMA*) and an editor in chief (EIC3) (from a high IF journal) did discuss these.

Reflecting the sample policies and guidance, there was also extremely limited discussion by interviewees regarding contributors' COIs (i.e. those involved in the development of a paper but who do not qualify for authorship). Only two journal representatives said that their journals do require contributors to disclose (and when I examined the online policies, this did not appear to actually be the case for one of these interviewee's journals). On the whole, when representatives of journals did mention contributors, they made it clear that it is typically required for such actors to be acknowledged, but not for them to disclose conflicts, as shown by the illustrative quotes in Table 5.5.

Table 5.5 Quotes regarding the disclosure of contributors' COIs

Interviewee	Quotes
P1	'We'd certainly ask that all people associated with the article are appropriately acknowledged, but I think I'm probably right in saying we haven't gone as far as asking those people for conflicts of interest as well'
EIC3 (high IF journal)	'We ask for a contributorship statement, so the authors have to say who did what to produce this article. And that would define whether they are authors or not. So there may be other people who aren't authors, and we wouldn't ask them for a declaration of anything. Because they're not authors.'
Thomas Garite, (EIC of <i>AJOG</i> )	'Occasionally you'll have someone who is identified by, as helping ... at the end of the article, but I don't know if they've ever been identified as having conflicts. So I don't even know if we have a policy about that'.
Annette Flanagan (Executive Editor at <i>JAMA</i> )	'Collaborators ... we don't require forms from them.'
Patty Bashkin (Executive Editor at <i>Neurology</i> )	'We list all of the contributors who do not qualify as authors, and we require them to state their role, their role has to be stated and they're put in a contributors' list, but we do not require them to do disclosures. Because they are not the authors and we would, we found that there has to be some point at which we have to let it go.'

These quotes demonstrate a lack of awareness and/or a reluctance within journal publishing to look beyond, or to broaden, the accepted understandings of who might be conflicted; this will be looked at further in the discussion section of this chapter (5.5).

As mentioned earlier in this section, there are specific types of contributors who can have a notable impact on the content of journal articles, in particular medical writers. As with the journal guidance and policies, however, most interviewees did not bring up the potential COIs of this actor group, as Table 5.4 shows, and there are limited requirements for them to disclose any potential conflicts (see also Chapter Six, Section 6.3.4). It is particularly interesting to note that only one of the four medical writers interviewed acknowledged that, as an actor group, they could potentially be conflicted.

Generally, interviewees seemed to feel that as medical writers do not qualify for authorship, any potential conflicts that they might have are not relevant. When asked whether their journal requires declarations of COIs from medical writers, a senior editor on a high IF journal said:

*'No we don't. Unless they're named on the by-line they wouldn't be regarded as an author. We wouldn't be asking them for conflict of interest. Because they're not taking responsibility for the study.'* (SE2)

The key argument here seems to be that only those who take responsibility for a study should have to disclose COIs (and therefore, implicitly, that only they will have COIs that could impact on an article).

Statisticians are another subgroup of contributors who were singled out by two interviewees, but who are rarely mentioned in the policies/guidance. *JAMA* previously, under the editor in chief Catherine DeAngelis, acknowledged in published commentaries (as recently as 2010) that statisticians' bias could potentially influence research. The journal implemented a policy in 2005 that required an independent biostatistician, employed by either an academic or government research institution, to perform analysis on any type of industry-sponsored study in which the data analysis had only been conducted by statisticians employed by the research sponsor (DeAngelis and Fontanarosa, 2010, Fontanarosa et al., 2005). However, in 2013, under the leadership of Howard Bauchner (who became editor in chief in 2011), the journal reversed the policy (McCarthy, 2013, Bauchner, 2013), and there was no mention of it in *JAMA's* documents that were included in my analysis. Bauchner (2013) stated that this was due to changes such as the introduction of clinical trial reporting guidance, greater access to trial protocols and statistical analytic plans, together with proposed regulations that require that companies seeking new product approvals provide complete access to clinical trial datasets.<sup>17</sup> Yet, in an interview that I conducted in 2013 (when the policy was still in force), a representative from the journal acknowledged in an interview that the

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<sup>17</sup> See Chapter Seven, Section 7.2, for more discussion on reporting guidance and study protocols.

requirement for an independent statistician had *'been a risk for us'*. When asked why, they replied, *'Well, you know, some commercially funded papers might not be coming to JAMA because of that'*. The reversal of this policy thus perhaps highlights a conflict for the journal editorial office itself: that fear of losing industry papers may cause them to produce policies that are attractive to industry.<sup>18</sup> Statisticians may also be involved in the analysis of studies other than clinical trials, to which the safeguarding measures listed by Bauchner would not apply. When another editor in chief (of a 'contentious case' journal) was asked whether statisticians (or other contributors) had to disclose COIs, they replied, *'No ... often we don't even know who those people are. They'll just be in the thank you and acknowledgements.'* (EIC2). This statement demonstrates that those who do not fit into the medical journal publishing industry's accepted, and institutionalised, understanding of authorship, and any potential conflicts that they may have, will remain unmanaged. Yet this failure to disclose statisticians' COIs poses a concern, because as one author who I interviewed pointed out, statisticians can have a great deal of control over the interpretation of data:

*'I know that people will pay someone to run statistical analysis ... And those people have control or manipulation of the data and may not necessarily be listed as an author.'* (A2).

Given the influence that this group of actors potentially has over how data are interpreted and presented in articles, it can be argued that they should have to disclose their role and any potential COIs that they have.

## **5.3 Authors' conflicts: types**

### ***5.3.1 Types of conflicts of interest***

The following section explores the ways in which the medical/health journal publishing industry conceptualises the types of COIs that authors can face: what it portrays as constituting COIs that require management, and what it does not. Analysis of the policies and guidance included in this research reflect what was

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<sup>18</sup> Journal editors COIs are discussed in more detail in Section 5.4.1.



found in my Literature Review (Chapter Two), showing that COIs can be divided into three categories:

- 1) Personal Financial
- 2) Funding/Grants
- 3) Non-Financial/Professional/Other

Table 5.6 depicts which of these categories each journal refers to in its guidance.

Table 5.6: Types of relationships that might lead to COIs for authors, as referred to by journals in their guidance for authors (High IF are those marked with an asterisk; shaded boxes represent no reference to an actor group)

Journal	Personal Financial	Funding/Grants	Makes a distinction between personal financial & grants	Non-Financial/Other
<i>NEJM*</i>	Y	Y	N	N
<i>The Lancet*</i>	Y	Y	N	Y
<i>JAMA*</i>	Y	Y	N	Y
<i>BMJ*</i>	Y	Y	Y	Y
<i>PLoS Medicine*</i>	Y	Y	N	Y
<i>Annals*</i>	Y	Y	N	Y
<i>BMC Medicine*</i>	Y	Y	N	Y
<i>CMAJ*</i>	Y	Y	N	Y
<i>JIM*</i>	Y	Y	N	N
<i>Mayo Clinic Proceedings*</i>	Y	Y	N	N
<i>AJC</i>	Y	Y	N	Y
<i>AJM</i>	Y	N	N	N
<i>AJOG</i>	Y	Y	N	N
<i>Birth Defects</i>	Y	N	N	Y
<i>Clinical Therapeutics</i>	Y	Y	N	Y

<i>Environmental Technology</i>	Y	Y	N	N
<i>IAOEH</i>	Y	Y	N	Y
<i>JAACAP</i>	Y	Y	N	Y
<i>JCP</i>	Y	Y	Y	Y
<i>JNCI</i>	Y	Y	N	Y
<i>Risk Analysis</i>	N	N	N	N

In the interests of clarity, and to reduce the chance of misunderstandings, it is helpful to make a distinction between personal financial COIs and funding/grants. The former involves personal, individual financial relationships. These can arise, for example, from an individual holding stocks in a company; receiving payment for research; or being paid honoraria for performing certain roles, such as giving presentations, undertaking consultations, sitting on advisory boards, or receiving patents. The latter relates to study- or organisation-level relationships, where the money does not go directly to the individual. The *BMJ*'s guidance makes this distinction, as shown in Box 5.1.

*Box 5.1: Extract regarding financial COIs from the BMJ Group Policy (BMJ Group, 2012a)*

<b>Personal financial interests</b>	'A personal financial interest exists when payments are made directly to an individual, whether as a salary or as fees or honoraria; or where an individual receives benefits from a third party who is not their main employer, such as a fellowship, equipment, writing or administrative assistance, or travel and accommodation expenses; or where an individual owns stock and shares, patents, or other assets.'
<b>Organisational financial interests</b>	'An organisational financial interest exists where the interest belongs at arm's length to the individual – for example, where payments are made to the individual's organisation rather than to their own bank account. Examples include: Research grants, funds for staff or department.'

However, as Table 5.6 shows, the majority of the journals in my sample do not make this distinction in their guidance and disclosure processes, and simply have the categories 'financial' (incorporating both personal financial COIs and funding/grants in the examples of interests that they give) and 'non-financial'. Although both are 'financial', this difference is important in terms of offering clarity regarding the types of interests that could affect research and resulting articles, and this thesis follows the lead of the *BMJ* and *JCP* and makes a distinction between them.

It should be noted that the data in Table 5.6 were derived from the examples my sample journals give of the types of relationship that can lead to COIs, regardless of whether they grouped them into two distinct categories. This table demonstrates that personal financial conflicts are the most discussed in the journals' authors' guidance, with all but one referring to them. Funding/grants are referred to by all but three of the journals. In contrast, seven journals do not discuss other/non-financial conflicts at all. The next three sections will explore the coverage of these types of conflicts in the sample policies and interviews in more detail, with a view to showing the narrow conceptualisation of the types of conflicts that authors can face, with certain ones focused upon while others escape attention, and may therefore remain undisclosed.

#### *5.3.1.1 Personal financial conflicts of interest*

Journals go into varying levels of detail regarding personal financial sources of conflict. Most provide illustrative examples (see Appendix III). These generally include: employment, stock ownership, honoraria, paid expert testimony and patents. However, specific amounts and time-spans that are considered to be relevant are often not given by journals, and in such cases it is up to the authors to decide what qualifies for disclosure. The ICMJE disclosure form asks users to report: 'all sources of revenue paid' (emphasis my own); however, the questions on the form do not require specific sums to be included, nor do they offer any direction in this regard (ICMJE, n.d.). Yet, as the following medical publishing critic argued, this information is important, in order that recipients of the disclosure might understand the extent of the interest and therefore be better able to judge the effect that it may have had:

*'There's a big difference between saying that last year I was paid by Merck to do one talk and they gave me a thousand dollars, versus saying that last year I was on the Merck advisory board and I got 50,000 dollars. You need that kind of detail to get a better picture of what the relationship is between the person and the drug company.'* (Joel Lexchin, Medical Publishing Critic)

While this may be true, it is worth noting that research has shown that even small amounts of money can subconsciously affect decision-making, evoking a sense

of obligation to return the favour (Dana and Loewenstein, 2003) (see Chapter Two, Section 2.5.1). Yet in the case of some journals, the threshold over which actors are required to declare an interest is very high: for example, *Mayo Clinic Proceedings* gives an example of financial involvement that can constitute a COI (and thus needs to be declared) as being ‘stock holdings (\$10,000 or 5% equity interest in a company)’ (Mayo Clinic Proceedings, 2013). This means that smaller financial interests, that may still have had an impact, will be excluded from disclosures.

The instructions on the ICMJE form specify that payments that were made over the previous ‘36 months’ must be declared; thus, journals that use this form presumably require this information from their authors. There was, notably, no discussion in the interviews or policies/guidance and disclosure forms of how future potential relationships may lead to current conflicts. The discussion on conflicts portrays them as being either a historical or current issue, and ignores agreements about future compensation (for example, future funding or employment).

#### *5.3.1.2 Funding/Grants*

The source of funding, as discussed in the introduction to this section, constitutes a type of financial conflict. For the most part, journals do not make a distinction in their guidance between the sources of funding – i.e. whether it is government or third-sector funding (see Appendix IV). The ICMJE’s Uniform Requirements document (ICMJE, 2015d) does not offer any information regarding the provenance of funding. However, its disclosure form (ICMJE, n.d.) does state that only funding from entities that ‘could be perceived to be affected financially by the published work’ needs to be disclosed, and that public funding does not need to be (it does not explain why):

‘Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be disclosed’. (ICMJE, n.d.)

As such, journals using this form would presumably not require disclosures of government and third-sector funding. It is also curious that charitable foundations (the exact definition of which varies from country to country) are considered here to be a public funding source, and also that they and academic institutions will never be affected financially by the work they support. The CSE's White Paper, on the other hand, advises that authors should 'disclose all sources of funding (government, corporate, other)' (CSE Editorial Policy Committee, 2012, p. 25). WAME also takes the position that research funding from 'government agencies, charities (not-for-profit organizations), and professional and civic organizations, which also have agendas that may be congruent or at odds with research findings' (WAME Editorial Policy and Publication Ethics Committees, 2009) should be declared. Some journals do request that non-commercial funding also be disclosed: *JIM* specifically states that authors should list 'governmental, industrial, charitable, philanthropic and/or personal sources of funding', and *JNCI* makes reference to 'commercial or other sources of funding' in its Author Instructions. Conversely, *IAOEH* states specifically that it only requires commercial funding to be disclosed, without explaining why.

Five interviewees described specific conflicts that can arise from charity/advocacy funding, and the problems that these potentially could entail. They argued that charities have vested interests in promoting their particular causes, as shown in the following quotes:

Table 5.7: Illustrative quotes from interviewees on the potential vested interests of charities

Interviewee	Quotes illustrating the potential vested interests of charities
A5	<i>'I think there is a naïve view that these disease advocacy organisations, unlike drug companies, have very pure motives: 'Find the cure to diabetes', how could that be a bad thing? As opposed to drug companies: they're obviously pushing their drug over other drugs. How can a group that is pushing diabetes awareness, or diabetes cure, how could that be a bad thing? Well, that's a bad thing if you're misallocating resources ... If diabetes accounts for 20% of the morbidity and mortality of a population, but is getting 50% of the national healthcare spending dollars, that's probably not good, and the diabetes association isn't going to complain if they're getting too big a share of the pie ... The readership needs to be more sophisticated, every advocacy organisation is going to have their biases. If the cancer society says that cancer is the biggest problem, that needs to be taken with a grain of salt.'</i>
Richard Smith (former EIC)	<i>'A lot of the grants you do get come from charities. They have a very particular view of the world. Not interested in research that upsets it.'</i>
MW2	<i>'Another reason that I don't like conflict of interests that just concentrate on financial ... isn't it the ICMJE that talk about sponsorship, they only want to know if you've received money from a commercial organisation? And not a government or a charity, and some of those have quite clear and quite extreme agendas. And as a reader, I absolutely want to know where that person's coming from. Whether it's a pro-life group, or a group with a particular axe to grind.'</i>

The majority of interviewees, however, appeared to feel that research funded by manufacturing sector companies was more likely to be biased than that which is funded by the public/voluntary sector. The 'profit-motive' (MPC3) and the requirement to satisfy shareholders were cited by interviewees as reasons to be more concerned over commercially-sponsored research than research that is funded by the government or third-sector. Authors and editors confirmed, when asked, that they would read articles from industry-sponsored research in a slightly more sceptical light than they would research funded by these other sectors:



Table 5.8: Illustrative quotes from interviewees on research funded by manufacturing sector companies

Interviewee	Quotes illustrating greater scepticism by interviewees of research funded by manufacturing sector companies
A4	<i>'Anything that's funded by industry, I automatically build in a certain scepticism ... about the degree to which the results are going to be generalizable to other patient populations. Because we've just been burned so many times.'</i>
A6	<i>'I suppose there's a perception that the privately funded research, or certainly pharmaceutical industry funded work, might have more conflicts of interest. That's the perception I hold, I'm not sure how true it is actually, but if I review papers I would just go over things with a little more scrutiny as whether there is any spin into the results or whatever.'</i>
MPC3	<i>'There's a profit motive. The government funded research, they don't usually make a profit, at least not in the US, their patents would go to publicly owned, and so the funder themselves is not going to get rich off of the research findings. The investigator, if they have favourable findings, may be able to get more funding, but that's a lot smaller pay-off than the company which would make a lot of money. So I think that's the difference.'</i>

However, this may have unintended detrimental consequences. Not only may it make authors reluctant to disclose industry funding, but also, as Richard Smith (former editor in chief of the *BMJ*), explained in an interview, *'the result of people disclosing will be that a whole lot of stuff gets discounted more than is appropriate.'* Indeed, two authors interviewed argued that knowing that an author has potential COIs could help lead them, as readers, to be biased and more sceptical of the information in the article:

Table 5.9: Illustrative quotes of interviewees' bias against articles written by authors with declared COIs

Interviewee	Interviewees on their increased scepticism of articles written by authors with declared COIs
A2	<i>'I think the bias is always to say, if they have a conflict of interest, they're always going to be biased ... The ultimate bias at the reader level may be that we can't trust the authenticity of this data in some capacity.'</i>
AE1	<i>'I just check how the paper looks and I make my own opinion, and I try not to read the disclosure first. I don't wanna bias myself. My advice to anyone actually that approaches a research paper, that it should be to just read the paper first, and then read the name of the people, and then read if there are any conflicts of interest. Because really, it doesn't matter who wrote the paper ... If the paper is good, it's a good paper.'</i>

While my interviewees generally agreed that industry funding is more likely to lead to COIs (due to the 'profit-motive' (MPC3)), there was an overall sense that public funding may also do so, although the conflicts may be less obvious or extreme. They therefore generally felt that all funding should be declared, regardless of its provenance, as this editor in chief argued:

*'It doesn't mean that because the funding's come from a government body that the view expressed, particularly on policy research, is going to be independent'* (EIC3).

The issue of the provenance of funding perhaps requires some clarity and consistency across medical journal publishing. Smith et al. (2009) contend that public choice theory has demonstrated that those funded by the public sector can potentially be biased. Evidence from the field of social policy has shown that academic researchers working with third-sector or government funding are also susceptible to producing research that satisfies the demands of (or at least does not overtly challenge the beliefs and interests of) their funders (Smith, 2010, Dreger, 2015) (see Chapter Two, Section 2.3.3). Indeed, certain types of non-commercial funding (for example, charity or advocacy funding) can lead to very particular types of conflict, such as vested interests in promoting particular causes. This suggests that all funding should therefore arguably be declared, regardless of source.

### 5.3.1.3 Non-financial/other conflicts of interest

Section 2.2 of Chapter Two gave a brief overview of the debates surrounding financial versus non-financial COIs. There is evidence that shows that non-financial interests, if they conflict with the primary ones, can also be problematic and result in bias that affects research (e.g. Saver, 2012, PLoS Medicine Editors, 2008, Marcovitch et al., 2010). As this editor in chief argued,

*'I know that what influences my writing is my personal background and my own personal beliefs, the people I know and have relationships with. And this is never probed or subject to competing interest statements' (EIC3)*

Non-financial relationships can have an influence on authors, and can potentially conflict with their research. There therefore arguably need to be processes in place to manage such COIs. Despite this evidence, WAME is the only professional publishing association that provides a comprehensive section in its guidance on non-financial COIs. It divides them into four distinct categories: academic commitments; personal relationships; political or religious beliefs; and institutional affiliations (WAME Editorial Policy and Publication Ethics Committees, 2009). While the ICMJE's Universal Recommendations argue that financial COIs are 'the most likely to undermine the credibility of the journal' (ICMJE, 2015d, p. 3), it does acknowledge that, conflicts can also occur for reasons, such as 'personal relationships or rivalries, academic competition, and intellectual beliefs' (ibid). However, its disclosure form (which is all that authors are likely to read) does not offer users any guidance on this matter. In its section entitled 'Relationships not covered above' (i.e. not financial), it simply states:

*'Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.'* (ICMJE, n.d.)

The CSE's White Paper does not discuss authors' non-financial conflicts at all, and nor does COPE's guidance.

Table 5.6 showed that other/non-financial conflicts are the type that is least discussed in the journals' authorship guidance, with that of seven journals not referring to them at all. While the guidance and policies generally give examples of what can lead to financial COIs, this is often not the case with other/non-financial conflicts, and even when they are given, descriptions of what constitutes 'other' are often vague, as the extracts from journals' guidance in Table 5.10 show.

*Table 5.10: Examples of journals' guidance regarding non-financial COIs*

<b>Journal</b>	<b>Information given in guidance regarding non-financial COIs (emphasis added)</b>
<i>AJC</i>	All authors must disclose any financial and <u>personal relationships</u> with other people or organizations that could inappropriately influence (bias) their work' (The American Journal of Cardiology, 2016)
<i>JACAP</i>	<i>JACAP</i> requires all authors ... to specify the nature of all biomedical financial and potential conflicts of interest, financial or <u>otherwise</u> ' (JACAP, n.d.)

These two journals' guidance, both from my 'contentious cases' sample, do not offer authors any further guidance on the 'personal' or 'other' relationships that should be declared; the problem of such limited information is not restricted to the journals from my 'contentious cases' sample, however: *JAMA* (from my high IF sample) only offers the following information to users of its guidance:

'Any other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing what is written in the submitted work.' (Journal of the American Medical Association, 2016)

It could be that journal editorial offices do not consider these types of COIs to be as problematic as financial ones. Alternatively, it may be that many are simply unsure as to how to effectively manage these more amorphous conflicts, as suggested by the following interviewee:

*'There was this huge debate about should we [the BMJ] just concentrate on financial conflicts of interest? And we tried to move away from it, it wasn't awfully successful and people said actually, conflict of interest around finance is easier to define.'* (Richard Smith, former EIC of the BMJ)

They therefore leave discussion of them, if any takes place at all, to ambiguous statements.

A minority of my sample journals (primarily those from my high IF journal sample) do give examples of what can lead to non-financial COIs (see Table 5.11), but these vary in detail and specificity, with the majority being quite vague. Their utility is therefore questionable. The publisher, PLoS, is alone in providing a comprehensive set of examples with explanations for all of its journals (including *PLoS Medicine*). This demonstrates that, while non-financial relationships that may pose COIs are more nebulous than financial ones, it is possible to provide a clear list of examples. Such information could assist actors in understanding what sort of non-financial interests may cause them to be conflicted.

*Table 5.11: Examples sample journals give of non-financial activities or relationships that can lead to COIs*

<b>Journal</b>	<b>Example of non-financial relationships that can lead to conflicts of interest</b>
<i>Annals</i>	'personal relationships (such as employment, consultancies, close colleague or family ties ... )' (Annals of Internal Medicine, 2014)
<i>BMC Medicine</i>	'Non-financial competing interests include (but are not limited to) political, personal, religious, ideological, academic, and intellectual competing interests.' (BMC Medicine, 2016a)
<i>CMAJ</i>	'conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion.' (ICMJE, 2015d)
<i>JNCI</i>	'personal relationships, or direct academic competition.' (The Journal of the National Cancer Institute, 2016)
<i>The Lancet</i>	'conflicts can also occur because of personal relationships or rivalries, academic competition, or intellectual beliefs.' (The Lancet, 2014)
<i>PLoS Medicine</i>	Non-financial competing interests include but are not limited to: Professional - Acting as an expert witness - Membership in a government or other advisory board - Relationship (paid or unpaid) with organisations and funding

	<p>bodies including nongovernmental organisations, research institutions, or charities</p> <ul style="list-style-type: none"> <li>- Membership in lobbying or advocacy organisations</li> <li>- Writing or consulting for an educational company</li> </ul> <p>Personal</p> <ul style="list-style-type: none"> <li>- Personal relationships (i.e., friend, spouse, family member, current or previous mentor, adversary) with individuals involved in the submission or evaluation of a paper, such as authors, reviewers, editors, or members of the editorial board of a PLOS journal</li> <li>- Personal convictions (political, religious, ideological, or other) related to a paper's topic that may interfere with an unbiased publication process (at the stage of authorship, peer review, editorial decision making, or publication) ... For example, authors are required to declare if they have served or currently serve on the editorial board of the journal to which they are submitting, have acted as an expert witness in relevant legal proceedings, or have sat or currently sit on a committee for an organization that may benefit from publication of the paper.' (PLoS Medicine, n.d.-b)</li> </ul>
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The generally limited focus on non-financial COIs in the journal guidance was reflected in the uncertainty of some of the interviewees working on journals regarding what could constitute non-financial COIs. For example, a managing editor on a speciality journal, when asked about them, responded by asking me to provide '*an example of a non-financial conflict*' (ME1). A senior editor on a high IF journal was also vague:

*'I'm trying to think of a non-financial conflict of interest other than the obvious that you would very much like your paper to be published, therefore you can actually consider that all authors have got a conflict of interest.'* (SE1)

However, while some interviewees were dismissive of, or unsure about, non-financial COIs, others did acknowledge that they too can be problematic: see Table 5.12. These interviewees argued that such conflicts can, in fact, potentially be more influential than financial ones: as EIC3 argued, personal situations, experiences and fundamental beliefs can have more of an effect than whether one has received some small remuneration. However, these interviewees acknowledged that there was a lack of self-awareness within the medical field of

the impact that non-financial conflicts can have, and they suggested that, because they are harder to quantify, the publishing industry would rather shy away from them than to confront them and establish ways to manage them.

Table 5.12: Illustrative quotes from interviewees on the problematic nature of non-financial COIs

Interviewee	Quotes illustrating the problematic nature of non-financial COIs
A3	‘I think they can be even more problematic. So for example, if you think of things like occupational therapy or physiotherapy, and you have a strong belief in drugs, drugs are helpful in reducing pain in the lower back, and that’s the only type of research that you promoted. As opposed to saying, ‘well, maybe yoga, maybe there’s different types’. So that’s a non-financial conflict of interest, but definitely a conflict of interest.’
EIC3	‘If you think about what motivates you to do things, and what motivates you to take a particular stance on a topic, is it money, are you really open to be bribed to say something? And if I wanted to get you to do something, could I get you to do it just by offering you 50, 100, 200 pounds? Or are your views about end of life right or wrong, life hereafter, are they actually more to do with personal conviction, what your parents believe, school friends, the clubs and societies that you belong to and the friends who you mix with? And more importantly, the articles or letters or talks that you’ve given in the past espousing a particular viewpoint. I think all of those latter things are actually far more influential on what stance you’re going to take on a topic, than who has employed you in the past and what you’ve been paid for it. And yet the competing interests form that we fill in are almost exclusively about who has paid you to speak at a conference and what grants have you received and what stocks and shares do you own. Very little on whether your mother has Alzheimer’s. And those sorts of things I think are profoundly more influential on the stances that we take ... The forms barely touch on that. They do not invite people to disclose any of those.’
Niall Boyce, Senior Editor, <i>The Lancet</i>	‘There are certain areas in medicine where there are conflicts of interest that are less tangible, and some people have views on certain medical issues, ethical issues even, which are very fixed, you could almost call them dogmatic ... Now that’s something which is very much a judgement call, that’s something which it’s not as simple as saying ‘does the person have stocks or shares in Company X?’
SE2	‘The biggest problem for us is probably around non-financial conflicts of interest, where there’s a real kind of vagueness and understanding over what that constitutes ... These things are not really recognised in science as being explicitly conflicts of interest. Or universally, they’re not part of a lot of journals’ requirements around COI disclosure. Or COI management.’
MW1	‘Because these non-financial conflicts of interest are harder to detect, and everyone has them, they could be more frequent and



	more potent than financial ones. ... Non-financial conflict of interest, it's fundamental, and because it involves us critiquing ourselves, you will find that those in power are quite reluctant to look at it.'
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This can be related to Gieryn's discussion of 'boundary work', which argues that the demarcation between science and other intellectual activities (such as political beliefs) can be a problem for scientists (Gieryn, 1983). Such conflicts are innate to scientific research, but are harder to manage due to their lack of tangibility.

As shown in Chapter Two, it can perhaps be argued that financial COIs are more problematic than non-financial ones, with them having a greater chance of impacting on the content of articles. The *BMJ* even states on its competing interest policy that it altered its stance in 1998 (see the editorial by Smith (1998) for more on the reasons behind this) to only asking authors and reviewers to disclose their financial COIs:

'We used to ask authors and reviewers about any competing interests, but we have decided to restrict our request to financial interests. This is largely a tactical move. We hope that it will increase the number of people who disclose competing interests. Our experience, supported by some research data, was that people often did not disclose them.' (British Medical Journal, n.d.)

According to Smith's editorial (Smith, 1998), this policy is based upon two studies which found that authors did not declare COIs to journals (Stelfox et al., 1998, Barnes and Bero, 1998). The *BMJ*'s guidance, quoted above, implies that the journal found that asking for all potential COIs to be disclosed led to less disclosure of both financial and non-financial COIs. According to the editorial, the *BMJ* hoped that 'narrowing the range may make it more likely that authors will declare competing interests' (1998, p. 292), but it does not make it clear as to why this would be the case. In his interview for this research, Richard Smith argued that it is because financial COIs are easier to define than non-financial, and thus people may be better able to recognise that they have them. The confusion is further added to by the *BMJ*'s Group Policy, which applies to its

journals, and which does discuss in detail non-financial interests, saying that they should be declared (BMJ Group, 2012b); further, the journal uses the ICMJE COI disclosure form for research papers, which includes an, albeit vague, section on non-financial relationships.

## **5.4 Other actors' conflicts of interest: types**

As discussed in Section 5.2, authors are not the only actors who may have COIs that could affect the content of journals. While it is authors' COIs that dominate the guidance/policies, there is some (though more limited) discussion of other actor groups. The focus of journals' instructions for authors on authors' COIs may be because these documents are aimed at this actor group. However, as Table 5.3 shows, some of the journal guidance/policies also refer to reviewers' and editors' COIs, as well as some other actors. Tables 5.1, and 5.2 demonstrate that guidance from other organisational actors (professional associations and publishers) also refer to other actor groups. Table 5.4 shows that some interviewees demonstrated an awareness that other actors besides authors may have COIs. The following section analyses the data to explore how, and to what extent, the COIs of other actors are conceptualised in medical/health journal publishing.

### ***5.4.1 Reviewers' and editors' conflicts of interest***

The professional associations representing publishers and journal editors (COPE, CSE, ICMJE and WAME) offer different amounts of information on what editors' and reviewers' COIs might be, and such advice is not always easily located in their guidance. COPE's documents state only that editors' conflicts can be 'financial, academic and other kinds' (COPE, 2011). Examples given for reviewers are 'personal, financial, intellectual, professional, political or religious' (COPE, 2013). CSE offers more detailed guidance on what could be considered COIs for editors: they should not be involved in decisions surrounding either their own manuscripts or those submitted by close colleagues (people from their department, research collaborators, co-authors) or competitors; nor should they

be involved on manuscripts relating to an issue from which they stand to gain financially (CSE Editorial Policy Committee, 2012). Similarly, CSE offers more information on what can constitute COIs for reviewers: any interest that might interfere with an objective review, such as: standing to make a financial gain (e.g. holding equity positions or stock options in a company whose product is discussed in the manuscript); gaining key knowledge about competitors' research which they use prior to publication, but without citing; having a study similar to that which they are reviewing, tempting them to delay the review until their own article has been accepted for publication; or holding strong views regarding the topic of an article which may bias them (ibid). ICMJE does not provide any examples of COIs for editors, though for other editorial staff it states 'financial interests or other conflicts (as they might relate to editorial judgments)' (ICMJE, 2015d, p. 4). It also does not offer any specific examples for reviewers. WAME suggests that reviewers will be conflicted if they: work for a company whose product was tested, or its competitors; or if they have 'special political or ideological agendas' (WAME, n.d.). Regarding editors' COIs, WAME says that they can arise if the editor (or close family members) has financial ties, or political/religious beliefs relating to authors or their work. WAME also says that they should not be involved in decisions over manuscripts that they have submitted, or those from authors in their academic department/institution.

With regards to the journals, the information they offer on what can constitute COIs for editors and reviewers varies (see Appendices V and VI). Three of the high IF journals and seven of the 'contentious cases' journals in my sample offer no information at all on reviewers' COIs, while four high IF and nine 'contentious cases' journals offer none on editors' COIs. As with authors, those journals that do provide guidance generally split COIs into either 'financial' (for example stocks or employment) or 'non-financial' (such as close or competitive relationships with the authors) categories. The amount of detail they provide in the examples is wide-ranging, and some (from both my high IF and 'contentious cases' samples) provide no examples of the types of conflicts that editors or

reviewers need to be aware of and disclose. For example, *BMC Medicine* simply states that

‘Editors and reviewers are also required to declare any competing interests and will be excluded from the peer review process if a competing interest exists.’ (BMC Medicine, 2016a)

Examples of what those competing interests might be are not given. Similarly, *JIM*’s only guidance with regards to reviewers is ‘We will also ask reviewers to provide a statement of competing interests.’ (Journal of Internal Medicine, n.d.) In contrast, journals such as the *BMJ*, *AJM* and *AJOG* provide detailed examples pertaining to the conflicts of editors’ that should be disclosed.

### **5.4.2 Journal owners’ conflicts of interest**

#### *5.4.2.1 The traditional publishing model*

Lundh et al. (2010) argue that the revenue streams within the traditional model of medical journal publishing pose a potential source of bias for journal owners (and, indeed, editors). Within this model, one of the main sources of journals’ revenue (other than subscriptions) comes from manufacturing sector companies in the form of advertising, supplements and reprints. Five interviewees (see Table 5.13) argued that these constitute significant COIs for these actor groups:

*Table 5.13: Illustrative quotes from interviewees regarding journals’ revenue from reprints*

<b>Interviewee</b>	<b>Quotes regarding journals’ COIs arising from reprints</b>
Leemon McHenry (Medical Publishing Critic)	‘The journals themselves are conflicted because they gain enormous amounts of money from advertising revenue from the pharmaceutical companies, but they also produce supplements to the journals which are entirely funded by the pharmaceutical industry. And they also get reprint revenue from the individual articles that get published. And if it’s a blockbuster drug ... those reprints go to hundreds, thousands, millions of doctors, then the journal and society that owns the journal is making enormous sums of money, astronomical sum of money.’
Joel Lexchin (Medical	‘The industry-funded studies will generate money in terms of reprints, which can be quite valuable for the journals. So there

Publishing Critic)	are a lot of reasons to want to publish research that comes out of industry.'
A5	'Many journals are fighting to survive, and publishing industry sponsored studies is oftentimes a major revenue source for them, not only because these companies are also buying ads in the journal, but oftentimes these journals make substantial money on reprints. And the only people who buy reprints nowadays I think are pharmaceutical companies. I don't know any academics who buy reprints anymore. For all of those reasons I think lower profile journals are in a much more vulnerable position.'
Richard Smith (former EIC of the <i>BMJ</i> )	'It seems to me that the conflicts of interest around publishing these big studies where you make an enormous amount of profit in reprints is absolutely enormous.'
Jason Roberts (Managing Editor)	'Journals face this dilemma which is, you could make hundreds of thousands of dollars – something that goes back to the society, and societies are struggling to make money. So there's an inherent conflict for the journals there.'

According to these interviewees, journals can make vast sums of money through publishing industry-sponsored research, which may be critical to their continuing publication, and therefore in some cases, to the survival of the organisations that own them. Editors and journal owners may therefore be more willing to publish articles that they know will generate greater income, and to overlook any issues from such companies.

The professional publishing associations (ICMJE, COPE, CSE and WAME) do all offer some guidance on these issues (ICMJE, 2009, CSE Editorial Policy Committee, 2012, COPE, 2011, COPE, n.d., WAME Editorial Policy Committee, 2009). Generally, they advise that journals have policies in place to ensure that editorial and advertising decisions are kept separate. ICMJE, COPE and WAME all state that journals should have formal policies on advertising that should be publicly available. COPE and CSE also advise that journals should publish the sources and details of their income (COPE, 2011, CSE Editorial Policy Committee, 2012) (yet as Section 6.3.2 of Chapter Six shows, none of the websites of the journals in my sample follow this advice and disclose such information). The

ICMJE's recommendations regarding advertisements in journals has previously stated that:

'Journals should not carry advertisements for products that have proved to be seriously harmful to health – for example, tobacco.' (ICMJE, 2009)<sup>19</sup>

The tension that can exist between profit and quality can cause conflicts between editors and journal owners. COPE's, CSE's, ICMJE's and WAME's discussions and policies on editorial freedom/independence all discuss the conflicts that can arise between journals<sup>20</sup> and their owners (COPE, 2011, COPE, n.d., CSE Editorial Policy Committee, 2012, ICMJE, 2014c, WAME Editorial Policy Committee, 2009). The documents produced by these professional associations explain that the policies, politics and commercial motivations of a journal's owner – including managing its revenue – may not always correspond with the publishing decisions of editors, whose primary interest should be in publishing articles based on their quality and suitability for the journal. If there are not sufficient mechanisms in place to protect editorial freedom, then the owners and editors may face conflicts between the commercial needs of the journal and what it publishes. Journal Oversight Committees, and other mechanisms for protecting editorial freedom, are discussed in Section 7.2.2.3 of Chapter Seven. This issue arose in just four interviews (one publisher, one editor in chief, one executive editor and one medical writer), with participants arguing that these can pose a conflict for journal owners when making decisions about which articles to publish.

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<sup>19</sup> The updated version, published in 2013, has amended this to, 'Journals should not carry advertisements for products proven to be seriously harmful to health.' ICMJE. 2013. *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* [Online]. ICMJE. Available: <http://www.icmje.org/icmje-recommendations.pdf> [Accessed 10th October 2014].

<sup>20</sup> As the heads of journals, this can also constitute a professional COI for editors in chief.

#### 5.4.2.2 The Open Access publishing model

Fully open access (OA) journals do not make money through subscriptions, reprints and supplements. Instead, they generally receive the majority of their income through author fees, as well as advertising.<sup>21</sup> Relying on author fees has the potential to pose a new form of conflict: as journals receive money for each article they publish, some may be less rigorous in their selection criteria, and less concerned about the COIs of the authors (Salem and Boumil, 2013). Four interviewees (a publisher (P1), Niall Boyce from *The Lancet*, a managing editor (ME2) and an author (A2)), echoed this concern:

*'You've got the economy of the journal, potentially depending on the number of papers it publishes. So that introduces a whole new potential conflict with editors who might have pressure put on them by their publishers to accept more material.'* (P1)

Referring to his past experience on an OA journal, the managing editor, ME2,<sup>22</sup> said that, *'We'd publish mediocre stuff to make money.'* This problem can be mitigated somewhat in hybrid journals – which offer authors the option of paying a fee and publishing OA, or publishing through the traditional model – if editors are not aware of which articles are going to be made OA:

*'We tried to design our submission processes ... in journals where we've got some open access material coming in as well as normal material as it were, the editors are not aware that that material is potentially open access. Those transactions are dealt with outside the editorial domain as it were.'* (P1)

However, this safeguard does not work with fully OA journals. The only mechanism in place, according to the publisher quoted above, is a journal's desire to publish only good quality material to maintain a high impact factor. However, three interviewees (one publisher, one editor in chief and one author) referred to the rise of 'predatory' journals, which typically email potential authors, offering to publish their articles for a fee (Clark and Smith, 2015). These

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<sup>21</sup> There are exceptions. For example, *PLoS Medicine* initially received a number of grants from philanthropic organisations.

<sup>22</sup> This Managing Editor did consent to be named; however, given the forthright nature of these comments, I have chosen to anonymise the individual to protect their identity.

journals (none of which were in my sample) exist purely to make money from authors who are less concerned with the quality of the journals they publish in than the matter of getting published (Beall, 2012, Beall, 2013). One senior editor who was interviewed expressed concern over whether editors of such journals would also require or scrutinise disclosures from authors, and suggested that it would therefore be easy to get biased research published in them. He argued that if people want research to be made freely accessible, they have to be prepared to assess them more for bias:

*'Researchers, readers, authors are going to have to decide what their priority is, how much they're willing to do in terms of searching for conflicts of interest, how much they're willing to do in terms of mentally de-spinning papers.'* (Niall Boyce, Senior Editor, *The Lancet*)

Very few of my interviewees discussed the COIs that OA journals might face (only four: one publisher, one managing editor, one senior editor and one author). Other interviewees, when discussing the OA model, generally spoke positively about it in terms of it making research more accessible.

#### **5.4.3 Medical writers' and other contributors' conflicts of interest**

As shown in Table 5.3, not all of my sample journals discuss the COIs of medical writers or other contributors. Similarly, only those professional associations specifically aimed at medical writers (AMWA, EMWA and ISMPP) refer to them. EMWA only states that medical writers should disclose relevant information about funding if required to by the journal (Jacobs and Wager, 2005). AMWA says that medical writers should disclose any pertinent professional or financial relationships (Mitrany et al., 2003, Hamilton and Royer, 2003). ISMPP states that potential COIs should be disclosed, though does not provide any examples of what these might be (ISMPP, n.d.).

*The Lancet* and *BMC Medicine* state that the funding of medical writers should be disclosed; there is no mention of any other conflicts that they may have which could have an impact on the articles they write, such as other financial or personal interests. *Annals of Internal Medicine* refers guidance users to EMWA's



guidance regarding medical writers, which, as mentioned above, only requires the disclosure of funding. With regards to contributors who have helped formulate consensus or guideline recommendations, *Annals* requires disclosures of COIs. *AJOG*, in addition to requesting a funding disclosure, states that medical writers' place of employment and a statement regarding compensation should be given. *JCP* does require that their 'pertinent professional or financial relationships have been disclosed in the Acknowledgment section'. However, no examples of such 'relationships' are given. *JACAP* mentions the 'pertinent professional or financial relationships' of medical writers and other contributors. *CMAJ* states that contributors must disclose competing interests, financial or other; as with *JCP*, it does not provide any examples. Thus, in the limited instances where medical writers' and other contributors' COIs are mentioned, the existing guidance seems to be limited and primarily focuses on funding. Even the guidance that does acknowledge that they may have other types of conflicts gives no examples as to what these might be.

## **5.5 Concluding discussion**

The findings outlined in this chapter demonstrate how there is a narrow conceptualisation of COIs in medical journal publishing industry, both in terms of what constitutes COIs and who it is that can have conflicts that need to be managed. It highlights the ways in which particular actor groups and types of interest are focused heavily upon, while others, which could also have an impact on the medical journal literature, are absent from the discussion and therefore many go unmanaged. This is problematic, as it means those conflicts could have an effect on the literature, unbeknownst to those reading it and using it to make policy and prescribing decisions.

As Section 5.2.1 discussed, analysis of the various policies and interview data shows that the potential conflicts of authors are almost ubiquitously referred to within the debate on COIs. However, the interpretation of authorship that has been accepted by the medical journal publishing industry is narrow –

most commonly the ICMJE's authorship criteria (ICMJE, 2015a) – with other models such as a contributorship one generally rejected. This section also showed that limited attention is given to the potential COIs of a number of other key actor groups, including editors, reviewers and journal owners. These actors have an influence over what is published, and thus any conflicts that they may have could have an impact on it. Yet, formal public policies by the journals about these actors' conflicts and how they should be managed is limited. The lack of awareness of these actors' potential conflicts was further evidenced in interviews, as discussed in Section 5.2.2.

Medical writers and other contributors, such as statisticians, were also noticeably absent from the journal guidance on COIs and the interviews. Medical writers, who have proven to be controversial due to their involvement in ghost-writing scandals, potentially can have a great deal of control over the content and development of an article; statisticians can likewise have influence over how data is interpreted and analysed. It is interesting that while the professional medical writing associations in my sample acknowledge that their constituents (medical writers) should disclose conflicts (mainly referring to funding, with less reference to other types of conflicts that they may have), other sectors' guidance, such as the publishers' and, most notably, the journals', which take precedence, do not. Interviewees (including medical writers) also showed a lack of awareness as to how these other actors might be conflicted: those who meet the accepted authorship criteria (generally the ICMJE's, which critics argue is flawed (e.g. Matheson, 2011, Moffatt, 2013, Helgesson, 2015, Bennett and Taylor, 2003)) are understood and accepted to potentially be conflicted; those who do not quite meet these criteria are not, and there was a reticence to consider that these actors may also have conflicts that require management.

There is a heavy focus in all of the guidance and policies on financial COIs; while not the case with all of the guidance, these are generally discussed, with examples given. The advice given on non-financial conflicts, however, is more limited. As interviewees suggested, these can be difficult to pin down, and the

medical journal publishing industry consequently appears to shy away from them. The *BMJ* states that it only asks authors and reviewers to disclose financial COIs in the hope that this will lead to greater disclosure of financial COIs. However, this is not a satisfactory solution. While it may lead to greater disclosure of financial conflicts (although there does not appear to be any evidence to prove this is the case), it does not solve the problem of how to manage non-financial/other COIs. COIs in medical journal publishing are primarily depicted as being financial, with non-financial/other potential conflicts marginalised in, or even excluded from, the debate. This means that potentially problematic conflicts, which could affect both research and resulting articles, may remain undisclosed. *PLoS Medicine* has produced a comprehensive list of examples of non-financial conflicts, which other journals, publishers and professional associations could perhaps learn from.

While financial COIs (both personal and funding) were given more attention, there is still a lack of detail on what they can constitute, such as with regards to the time period in which they may have occurred, and the amounts. There also appears to be greater concentration given to funding from commercial sources rather than public ones; due to the heavy attention that the data gives to the former, it has inevitably been of principal focus to the discussion within this thesis. While the more egregious and publicised cases of ‘data-spinning’ in journals has arisen from research sponsored by the pharmaceutical and tobacco industries, as interviewees pointed out, public funding can itself entail conflicts, so should not be ignored. Yet the ICMJE disclosure form, which is the one most commonly used by the journals, only requires funding from private sources to be disclosed; government and third-sector funding do not need to be. This, however, is at odds with guidance from WAME and CSE, which leads to another point: the guidance from the various associations is at times different, which could cause confusion for its users. The ICMJE also conflates public and charity funding. Ideally, all funding information should be disclosed, regardless of its type.

Hence there appears to be a narrow conceptualisation of COIs, both in terms of who it is that has conflicts that require management, and the types of conflicts that need to be managed. The ideas surrounding COIs are informed by the thinking of actors working within medical journal publishing, who may themselves be conflicted and have their own agendas, as well as being so immersed within the institutional environment that they are unable to see outside and beyond it. The narrow ideas on COIs that they develop are materialised in the form of the various guidance and policies. There is limited opportunity for new or alternative ideas to enter the institutional environment. There are occasional instances where individual journal guidance will consider other types of interest, or have requirements for a wider range of actors, but this chapter has shown that these are not the norm. It has also shown a reluctance to contemplate alternative ideas; when asking about non-financial COIs, for example, the topic was dismissed by the majority of interviewees as being too complicated, while confusion was frequently expressed when I tried to delve into their understanding of what other actors beyond authors (and occasionally editors and reviewers) might have conflicts that could impact on the journals.

Current understandings surrounding COIs thus appear to be limited, and therefore certain types of interest, which may pose a conflict, and particular groups of actors who may be conflicted, may escape management. For example, the authors of a study on treatment for mild gestational diabetes during pregnancy (Landon et al., 2009), which allegedly put protocol ahead of subject safety, resulting in a trial design that exposed control subjects to excessive risk of harm, were able to state that they had no disclosures to make as the journal asked only for financial ones (Stell, 2010) (see Chapter Two, Section 2.3.3). As discussed in Section 2.3.1.2 of Chapter Two, journal editors can face COIs that can affect their journals, yet there remains limited attention given to this actor group. Such potential conflicts, which could adversely affect medical/health publications, may therefore escape attention and potentially bias the literature. Conceptualisations both of interests that can lead to COIs, and who it is that

might be conflicted, thus need to be broadened, so that they might then be effectively regulated.

## **CHAPTER SIX: RESULTS**

### **Managing conflicts of interest in medical journal publishing: Disclosure**

#### **6.1 Introduction to the Chapter**

Chapter Five examined the policies and guidance developed by the medical journal publishing industry, together with interviews conducted across the stakeholder groups, to examine how COIs are conceptualised, both in terms of what they are and which actors can have conflicts that require management. This chapter now examines, through the data (drawing on both the guidance and policies, and my interviews), how these COIs are managed. It looks at which groups of actors whose COIs are managed, and which are not. The chapter looks at how voluntary disclosure is the primary method used to manage COIs: all of the sample policies and guidance consistently refer to it as the process through which COIs are managed in their sections on conflicts, emphasising its importance, and this was further reflected in the interviews with actors, who all focused on disclosure when exploring their understandings of how conflicts are managed.

Section 6.2 explores how the medical journal publishing industry presents, and the actors within it consequently understand, disclosure to be the main and most effective mechanism for handling COIs. The chapter also considers, in Section 6.3, which groups of actors are in practice requested to disclose, and in what format. This work demonstrates, conversely, which actor groups are not required to disclose, and the chapter considers the possible implications of this: there will be conflicts that could potentially impact on the medical literature that are unlikely to be openly identified through this system.

The chapter also looks at what the data suggest is done with disclosures in practical terms – if and how they are presented to journals’ audiences – and how effective this method of dealing with COIs appears to be. The final section (Section 6.4) assesses the strengths and weaknesses of disclosure to see whether it is a sufficiently robust system to manage COIs in medical journal publishing. While disclosure is certainly a useful process in many ways, this section shows that there are inherent weaknesses in it: it is not an infallible method and would benefit through being supported by other systems (see Chapter Seven).

## **6.2 Emphasising disclosure**

In their guidance and policies, the professional associations that represent medical/health journals place a particularly strong emphasis on disclosure as a means of managing actors’ COIs. The ICMJE states that those involved in publishing (which it lists as being: authors, peer reviewers, journal editors and editorial staff) must disclose their COIs:

‘All participants in the peer-review and publication process ... must disclose all relationships that could be viewed as potential conflicts of interest’ (ICMJE, 2013)

WAME outlines the key elements that should be present in journals’ COI policies in its document on COIs (WAME Editorial Policy and Publication Ethics Committees, 2009). The section of this document that describes how COIs should be managed is entitled ‘Declaring and Managing COIs’. This demonstrates that disclosure is seen as the way in which COIs should be managed:

‘managing COI depends on disclosure because it is not possible to routinely monitor or investigate whether competing interests are present.’ (WAME Editorial Policy and Publication Ethics Committees, 2009)

After defining COIs, CSE likewise, provides a section on disclosure, again highlighting the focus placed on its role in managing conflicts. CSE states that:

‘Journals should require disclosure of all conflicts of interest from everyone involved in the publication process: editors, reviewers, editorial board members, editorial staff, and authors.’ (CSE Editorial Policy Committee, 2012, p. 11)

COPE's resources are less focused on disclosure, with its guidance documents for publishers and editors stating that journals need COI policies, but not offering much advice on what these should consist of (COPE, 2011, COPE, n.d.). The emphasis on disclosure as the norm for management of COIs in medical/health journal publishing is further evidenced in the COI guidance and policies of my sample publishers. In their guidance on COIs, all of the publishers' documents in my sample state that relevant stakeholders should disclose conflicts (see Table 6.1). The journals in my sample (regardless of impact factor (IF)) are likely to, at least in part, develop their policies on the basis of the guidance provided by the professional associations and by their publishers. Perhaps as a result of this, they all use disclosure as the primary means for managing COIs; some explicitly explain in their COI policies that certain stakeholders will be required to disclose, while others simply ask disclosure questions as part of their submission processes. The centrality of disclosure in managing COIs was further reflected through the focus interviewees placed on it. Disclosure was seen by the majority of interviewees, across the spectrum of actor groups, as being fundamental to the management of COIs. In the words of one interviewee, it is considered to be *'the best way to go'* (Melanie Slavitch, Managing Editor, *CMAJ*).



*Table 6.1: Extracts on the disclosure of COIs from publishers' policies/guidance*

<b>Publisher</b>	<b>Extract from policy on COI disclosure</b>
Wiley	'Editors, authors, and peer reviewers should disclose interests that might appear to affect their ability to present or review work objectively.' (Deakin et al., 2014)
Elsevier	'Undeclared financial conflicts may seriously undermine the credibility of the journal, the authors, and the science itself ... Full disclosure about a relationship that could constitute a conflict – even if the person doesn't believe it affects their judgment should be reported to the institution's ethics group and to the journal editor to which a paper is submitted. All publishers require disclosure in the form of a cover letter and/or footnote in the manuscript.' (Elsevier, n.d.)
T&F	'Authors must declare any potential conflict of interest – be it professional or financial – which could be held to arise with respect to the article. Authors must disclose all sources of funding for the research reported in the paper' (Taylor & Francis, 2014)
OUP	'How can I be sure if I should declare something?' (Oxford University Press, 2014)
Springer	'Authors and reviewers should declare all conflicts of interest relevant to the work under consideration' (Springer, 2013)

The ubiquity of disclosure as a way of regulating COIs in medical/health journal publishing is not surprising; it plays a key role in the management of COIs across medicine, as well as other professions such as business and law (Cain et al., 2005a) (see Section 2.6, Chapter Two). Disclosing conflicts when submitting articles is arguably beneficial; however, it also has inherent weaknesses (see Section 2.5.1 of Chapter Two for a debate about its strengths and weaknesses). Other potential processes that could assist in the management of COIs (such as peer review and non-publication policies) are looked at in more detail in Chapter Seven.

## **6.3 Who is required to disclose, and how is this information gathered?**

### ***6.3.1 Disclosure of authors' conflicts***

The previous chapter explored which stakeholders the medical/health journal publishing industry portrays as potentially having COIs that require

management. It showed there to be a particular preoccupation with authors' conflicts, often to the exclusion of considering the potential COIs of other actors involved in medical/health journal publishing. Reflecting this, all of the policies and guidance in my sample require disclosure from authors, and all interviewees referred to them. Authors interviewed generally stated that, in their experience, they were always asked to disclose:

*'I would say that most articles I am signing something about conflicts.'* (A5)  
*'That's [disclosure] quite universal, I've seen it almost all in, no matter what the impact factor the journal has, that's always the case.'* (A6)

As discussed in Section 6.2, all of the professional publishing associations in my sample (ICMJE, WAME, CSE and COPE) advise that authors disclose potential COIs (with an emphasis on financial interests). However, the amount of guidance they offer on *how* they should disclose varies, with the ICMJE offering the most. It has a disclosure form (ICMJE, n.d.): journals either use it in its existing format, or adapt it in order to devise their own. The organisation also provides the following advice on how authors should report their COIs:

*'Articles should be published with statements or supporting documents, such as the ICMJE conflict of interest form, declaring: Authors' conflicts of interest; and Sources of support for the work ... and whether the authors had access to the study data. ... To support the above statements, editors may request that authors of a study sponsored by a funder with a proprietary or financial interest in the outcome sign a statement, such as "I had full access to all of the data in this study and I take complete responsibility for the integrity of the data and the accuracy of the data analysis."' (ICMJE, 2014a)*

The organisation thus advises that either forms or statements disclosing conflicts should accompany published articles. WAME likewise says that conflicts should be declared in writing (by authors and reviewers), but it does not offer any further advice on the format through which these disclosures should be made (e.g. whether forms should be provided by the journals for authors to complete, or that specific written statements should be given by the authors). As mentioned in Section 6.2, CSE also recommends that authors should disclose; however, it does not make any comment on how disclosures should be made. COPE only says, in its guide for new editors (Rees, 2011), that journals

may want to include a competing interest declaration for authors as part of their submission process.

The guidance of all of the publishers in my sample states that authors' conflicts should be disclosed. Other than Springer, they all provide advice on how this can, or should, be achieved. Elsevier suggests that authors should disclose conflicts in a section of their articles, which means that they will be available for readers to view. Wiley says authors should provide disclosure statements and that editors should publish these, so again, readers will have access to them. T&F and OUP both say that authors should declare their COIs upon submission; however, neither of them advise on how this information should then be conveyed to the readership. For the most part the journals' policies follow the guidance offered by their publishers, although this is not always the case. For example, *JAACAP* (which is published by Elsevier), appears to only ask authors to disclose on their submission form (they are not asked to include a statement in the text); similarly, *AJM* (also published by Elsevier) only requires that authors provide a statement in a letter on institutional paper, with no mention of how any relevant information in this is then passed on to readers. The journals appear to be somewhat autonomous from their publishers and are able to set their own policies, which are not necessarily as stringent as those recommended by their publishers.

All of the journals in my sample request that all authors provide disclosures of financial COIs and sources of funding, though their methods for acquiring disclosures, and what they then do with them, vary (see Table 6.2). It is often just the submitting author who compiles this information; this individual is thus reliant on their co-authors' honesty (and, in turn, the journal must trust that the lead author has acquired this information from each of their co-authors). Journal requirements for disclosing non-financial COIs are less common: see Chapter Five, Section 5.3.1 for discussion on the focus upon financial COIs in medical journal publishing.

The format through which journals require disclosures to be made is shown in Table 6.2. (The table also shows what journals require from authors if they have no conflicts.) Disclosure by authors is generally made through: the completion of forms; statements in correspondence to the journal or on the manuscript; or answering questions in the submission process (it is most often a combination of these). This table shows that each journal differs in its requirements on how disclosures should be made. One author felt that the requirements depend on the IF of the journal: the higher IF journals tend to be more rigorous and require the completion of forms, while the lower IF ones generally have less thorough procedures, relying more on simple summarising statements. This reflects the journals in my sample: as the table shows, all but two (the two OA journals: *BMC Medicine* and *PLoS Medicine*) of the high IF journals ask authors to complete a disclosure form (either their own or the ICMJE's), while only one 'contentious cases' journal (*JCP*) has a form (that it developed itself). All of the high IF journals also require that a COI statement be included with the manuscript, other than *NEJM*, while *JIM* and *JNCI* only ask that funding sources be listed. From the 'contentious cases' journals, *JCP*, *AJC*, *AJOG*, *Clinical Therapeutics*, *IAOEH*, *Environmental Technology* and *Birth Defects* say that authors should provide a statement in their manuscripts summarising conflicts. However, *AJM*, *Risk Analysis* and *JAACAP* only ask for conflicts to be disclosed in the submission process; no advice is given on how authors should present this information to readers (or how the journal will do so). Interviewees' perceptions of the useful attributes of such disclosure forms are summarised in Box 6.1. However, while these forms can be useful, summaries on articles can also be helpful, as they enable readers to appropriately contextualise the content:

*'At least with a statement at the end of the manuscript, then you can scan through it fairly quickly and see if anybody's got any major conflicts of interest.'* (SE1)

Further, as one managing editor of a small, speciality journal explained when interviewed, he does not have the time to collect detailed disclosure forms from each author, and thus just asks for one general statement:

*'How the hell am I gonna get those forms out of every author? ... I don't give them a form because I know that I'd never get a bloody thing published if I had to wait for every author to fill that out. So I just get a statement ...'*  
(Jason Roberts, Managing Editor)

Table 6.2: Journals' COI disclosure requirements for authors (High IF journals are those marked with an asterisk)

Journal	Disclosure format	No conflicts
<i>NEJM</i> *	- Complete ICMJE disclosure form (available online with the full text of each article) (ICMJE, n.d.)	ICMJE form requires this to be explicitly stated.
<i>The Lancet</i> *	- Complete ICMJE disclosure form. - At end of text – under heading 'Declaration of interests' – all authors must disclose any COIs. - All sources of funding should be in the acknowledgments. - Role of funding source should be in the methods section.	ICMJE form requires this to be explicitly stated. Not possible to establish how journals handle this information.
<i>JAMA</i> *	- Complete ICMJE disclosure form. - COIs should also be disclosed in the acknowledgment section of the manuscript.	ICMJE form requires this to be explicitly stated. Not possible to establish how journals handle this information.
<i>BMJ</i> *	- Statement given at submission. - Articles other than research papers: list potential conflicts. - Research papers: ICMJE form and statement within submitted manuscript summarising info in form.	- Statement on paper declaring there are none. - ICMJE form requires this to be explicitly stated. Not possible to establish how journals handle this information.

<i>PLoS Medicine*</i>	<ul style="list-style-type: none"> <li>- Competing interest statement (filled in at submission).</li> <li>Not clear if this is made available to reviewers and readers.</li> </ul>	<ul style="list-style-type: none"> <li>- Provide statement during submission process.</li> <li>Not possible to establish how journals handle this information.</li> </ul>
<i>Annals*</i>	<ul style="list-style-type: none"> <li>- Statement summarising all authors' COIs at submission.</li> <li>- If invited to revise, each author completes an ICMJE disclosure form.</li> </ul>	<ul style="list-style-type: none"> <li>- ICMJE form requires this to be explicitly stated.</li> <li>- Confirm at submission.</li> <li>Not possible to establish how journals handle this information.</li> </ul>
<i>BMC Medicine*</i>	<ul style="list-style-type: none"> <li>- Provide section at end of manuscript listing competing interests.</li> </ul>	<ul style="list-style-type: none"> <li>- Must provide statement included in manuscript.</li> </ul>
<i>CMAJ*</i>	<ul style="list-style-type: none"> <li>- Complete ICMJE disclosure form.</li> <li>- Authors must state their COIs explicitly in the manuscript, on a page following the title page.</li> </ul>	<ul style="list-style-type: none"> <li>- Authors must state explicitly on manuscript whether potential conflicts do not exist.</li> <li>- ICMJE form requires this to be explicitly stated.</li> </ul>
<i>JIM*</i>	<ul style="list-style-type: none"> <li>- Journal's own disclosure form.</li> <li>- Acknowledgments should include a statement disclosing funding sources.</li> </ul>	<ul style="list-style-type: none"> <li>- If no competing interests, must provide a statement declaring this with manuscript</li> </ul>
<i>Mayo Clinic Proceedings*</i>	<ul style="list-style-type: none"> <li>- Statement revealing any financial COIs and financial funding support on title page.</li> <li>- Journal's own disclosure form.</li> </ul>	<ul style="list-style-type: none"> <li>- Check box on form declaring none.</li> <li>Not possible to establish how journals handle this information.</li> </ul>
<i>JNCI</i>	<ul style="list-style-type: none"> <li>- Journal's own disclosure form for accepted manuscripts.</li> </ul>	<ul style="list-style-type: none"> <li>- No comment.</li> </ul>

	-Section in manuscript before the acknowledgments disclosing funding sources.	
<i>AJC</i>	- Statement on manuscript.	- No comment.
<i>AJM</i>	- Provide statement in letter produced on institutional paper. Not possible to establish how journals handle this information.	- Must state in letter. Not possible to establish how journals handle this information.
<i>AJOG</i>	- Provide statement on title page.	- Must state on title page.
<i>Birth Defects</i>	- List in the cover letter, in the manuscript (in the footnotes, COI or acknowledgments section), and in the online submission system.	- Must state at submission. Not possible to establish how journals handle this information.
<i>Clinical Therapeutics</i>	- COI statement at end of text.	- No comment
<i>Environmental Technology</i>	- Include a disclosure statement on title page.	- No comment.
<i>IAOEH</i>	- Summary statement should be given before references. - COI form (though none given; ICMJE form is used as an example).	- Must state on manuscript.



<i>JAACAP</i>	- Declare on Manuscript Submission Form.	- Must state explicitly on manuscript.
<i>JCP</i>	<ul style="list-style-type: none"> <li>- Complete Journal's 'Authorship Statement, Copyright Transfer, Financial Disclosure, and Acknowledgment Permission' form.</li> <li>- Title page: disclose 'financial and material support'.</li> <li>- Acknowledgments: list 'any relevant financial disclosure'.</li> </ul>	- Must provide statement, which will be included with article.
<i>Risk Analysis</i>	- Journal has list of questions that it asks during submission, which is completed by the main author on behalf of others.	<ul style="list-style-type: none"> <li>- Must tick box on form.</li> <li>Not possible to establish how journals handle this information.</li> </ul>

*Box 6.1: Interviewees' perception of the uses of disclosure forms*

<b>Useful attributes of disclosure forms</b>
<ul style="list-style-type: none"><li>• Editors can use the detailed information included in the forms when making decisions over whether to publish articles.</li><li>• If published and made available to readers, the forms offer more detail and consistency than simple statements.</li><li>• Completing and signing forms increases accountability, and authors are thus arguably more likely to disclose relevant conflicts.</li><li>• The forms offer journals protection – they serve as ‘<i>cover your ass</i>’ documents (Jason Roberts, Managing Editor) – as they demonstrate that journals have requested such information from authors and published articles on the basis of this.</li></ul>

Several journals, however, differ between what they ask to be disclosed on the manuscript, and what they require to be declared on the forms. For example, *JIM* asks that authors declare *any* conflicts on its COI form. However, on the manuscript itself, they are only asked to declare funding sources – they do not have to declare personal financial or non-financial conflicts. *JCP*'s disclosure form asks authors to declare ‘personal affiliations’, but they are only required to provide financial and funding disclosures on their papers (or to explicitly state if there are no COIs). This raises the question as to what is done with this additional information, and why it is not considered necessary for readers to be informed of it.

The ICMJE has developed a disclosure form which journals can either use as it stands, or adapt to develop their own (ICMJE, n.d.) (Drazen et al., 2009). The organisation hoped that this would help to ‘facilitate and standardize authors’ disclosures’ (ICMJE, 2015d, p. 4), yet its success on this front appears to be limited. Of the seven journals in my sample that are members of the ICMJE, six require authors to complete the ICMJE disclosure form (*PLoS Medicine* does not). Eight other journals in my sample are signatories to the ICMJE (but are not

members), but none of them use the organisation's disclosure form. Comments made by both editors and authors in interviews provide insights into why this may be the case, with them arguing that it is not user-friendly for authors:

*'The ICMJE, they ask for, it's a great big long checklist. Massive checklist that I think is probably a bit unworkable, or a bit off-putting.'* (Elizabeth Moylan, Managing Editor)

*'The ICMJE form ... I have a problem with that form actually ... I always feel for people who have others who need to fill it up.'* (A6)

Thus, while interviewees generally felt there was a need for a standardised form which could be used across different journals, the data suggests that the ICMJEs attempt, as it stands, is not perceived to be user-friendly enough to perform this role.

The ICMJE recommends that articles should be published with COI forms or statements accompanying them. Likewise, WAME suggests that 'Journals should publish all relevant COI disclosures with the publication' (WAME Editorial Policy and Publication Ethics Committees, 2009). CSE and COPE do not advise on whether or not disclosures should be published. In terms of the publishers, Elsevier and Wiley advise upon publication of authors' disclosures; the other publishers in my sample do not comment on what should be done with them. As Table 6.2 shows, most of my sample journals publish statements disclosing some author COI information (only *Mayo Clinic Proceedings* and *Risk Analysis* fail to mention at all in their policies what they do with disclosures).

What journals require to be included in these disclosure statements also varies, as this interviewee explained:

*'Some journals publish everything; some journals publish selective things. Some journals, it appears, don't publish very much at all. And the detail of what they publish also seems to vary considerably. So this seems to be a pretty haphazard thing that happens.'* (Joel Lexchin, Medical Publishing Critic)

Some journals will publish disclosures of financial and non-financial COIs and funding sources; others will only publish financial COIs and funding sources; and

some will only publish funding sources. Two journals rely on the individual judgment of the editors, saying that disclosures will be published at their discretion. There is a lack of consistency in how information is published, even amongst those journals that use the ICMJE's disclosure form. While some ensure that a summary statement is also included with the articles, others simply publish the forms, or provide links to them for readers.

Some interviewees argued that simply publishing the detailed forms for readers to peruse is not actually useful because they are too long and contain too much information; it is not likely that many readers will have the time to check them and therefore remain oblivious to any potential conflicts:

*'The members of the ICMJE are all requiring this form for authors, but only a handful are making them publicly available in an easy way. So some journals will just publish the form, so you read an article and then you click and you go online and you have to literally thumb through pages of the pdf to see, and if you have 25 authors you are looking through five pages each.'*  
(Annette Flanagan, Executive Editor)

While there is an emphasis placed on the process of disclosing as a solution to the problem of COIs, this quote reiterates the question of what is actually done with these disclosures in practice and to whom it is the authors are supposedly disclosing to: is the disclosure simply for the editors, or will the information also be made available to reviewers and/or readers? Is it just a pro forma exercise? These queries apply not only to the ICMJE form, but to the disclosure process in general; concerns surrounding the process of disclosure are looked at further in Section 6.4.2.

### **6.3.2 Disclosure of editors' and editorial staff's conflicts**

While disclosure of authors' conflicts, albeit through varying formats, is fairly ubiquitous across my sample journals, this is not the case with other actor groups involved in medical/health journal publishing, such as editors and editorial staff; this finding is similar to that of Haivas et al.'s study (Haivas et al., 2004). The professional publishing associations all acknowledge that editors may have COIs, and provide some advice on how these should be disclosed. As

well as suggesting that editors should not work on articles over which they may have a conflict, the ICMJE says that they should publish regular disclosure statements of journal staff (ICMJE, 2015d). COPE also suggests that editors should publish:

‘lists of relevant interests (financial, academic and other kinds) of all editorial staff and members of editorial boards (which should be updated at least annually)’ (COPE, 2011).

CSE recommends that everyone involved in the publication process, including editors and their staff, should disclose COIs, but does not provide any more advice on this in relation to editors (CSE Editorial Policy Committee, 2012). WAME states that a policy addressing editors’ COIs should be published (WAME Editorial Policy and Publication Ethics Committees, 2009), but does not offer any suggestions on the development or content of such policies. It does point out that some journals publish editors’ disclosures (it does not provide examples; however, Table 6.3 shows which journals in my sample do so), but acknowledges that this is not standard practice, and does not give advice either way. The professional association that represents the pharmaceutical industry, ISMPP, and the medical writing associations EMWA and AMWA, do not remark upon editors’ COIs (this is likely because it is not relevant to their audience). Interviewees representing these associations did not discuss editors’ COI.

Wiley’s guidance makes it clear that editors and their staff should disclose their COIs, and says that this information should be published on the journals’ websites (Deakin et al., 2014). Elsevier, on the other hand, while acknowledging that editors may be conflicted, does not advise on how these should be managed. Oxford University Press (OUP) simply says, in its ‘Information for Authors’, that editors will not be involved with manuscripts if they have potential COIs (Oxford University Press, 2014); however, OUP’s guidance does not appear to actually advise editors to disclose potential conflicts anywhere. Springer does not mention editors’ COIs in its guidance for editors (it only refers to authors and reviewers as having the potential to be conflicted) (Springer, 2013); likewise,

Taylor and Francis (T&F) does not refer to editors' COIs in its editors' guidance (Taylor & Francis, 2014).

As with the publishers' guidance, discussion of editors' COIs in the journals' policies (shown in Table 6.3) is more limited than that on authors' COIs, despite the fact that the professional publishing associations do advise journals to have systems in place for managing such conflicts. The requirements in the policies vary (with Table 6.3 showing that there are, notably, more disclosure requirements for editors amongst the higher IF journals than the 'contentious cases' ones). Some journals ask that editors publicly disclose and recuse themselves from working on articles over which they may be conflicted, although it is generally not made clear who they will disclose this information to (only *AJM* and *AJOG* clarify this, stipulating on their websites that editors' disclosures will be filed with the journal's editorial office and updated annually). Despite ICMJE's, COPE's and Wiley's recommendations that conflicts be disclosed on journal websites, only six of the journals in my sample do so. Members of the ICMJE wrote an article (which is published on the member journals' websites), stating that 'Editors should publish regular disclosure statements about potential conflicts of interests related to the commitments of journal staff' (Davidoff et al., 2001), yet of the seven ICMJE member journals in my sample (*Annals of Internal Medicine*, the *BMJ*, *CMAJ*, *JAMA*, *The Lancet*, *NEJM* and *PLoS Medicine*), only four publicly declare their editors' COIs on their websites (*Annals*, the *BMJ*, *CMAJ* and *PLoS*). On the basis of the policies that they have made publicly available, *The Lancet*, *JAMA* and *NEJM* do not appear to require editors to disclose conflicts, simply stating that they should not work on articles over which they may be conflicted. When asked whether the journals they publish publicly declare editors' conflicts, a publisher, acknowledged that, '*It varies, to be truthful*' (P1). Policies appear to often only require the disclosure of conflicts internally at a journal, without them being made public, as the following interview quote from a managing editor of a high IF journal illustrates:

*'From our editors in chief, we're asking for declarations. We're not declaring them publicly, but we're knowing about them in-house. I've never*

*had to openly declare them, but I wouldn't handle my best friend's manuscript through peer review.'* (Elizabeth Moylan, Managing Editor, *BMC Medicine*)

Despite the fact that some of the journals demonstrate an awareness of the need to manage editors' COIs, they do not always appear to put this into practice. For example, *The Lancet* published a commentary piece (James and Horton, 2003) discussing editors' (and reviewers') COIs, yet despite this detailed discussion of the ways in which such actors can be conflicted, reference to them is lacking elsewhere on the journal's website. *Annals of Internal Medicine* claims, in its COI policy, that it 'discloses editors' financial and academic relationships', yet in practice these do not appear to be provided on its website. The biographies of the editors, while providing information on their affiliations and research interests do not make any mention of any possible financial COIs, and do not mention the terms 'conflict of interest' or 'competing interest' (*Annals of Internal Medicine*, 2015). The *NEJM*'s policy states that 'none of the *NEJM* editors should have any financial relationship with any biomedical company' (*New England Journal of Medicine*, 2016), and thus it may be assumed that none of its editors have any relevant financial COIs (although it would appear from this statement that they can have non-financial ones). However, in 2000 Dr Jeffrey Drazen was appointed EIC of the journal, despite having ties with the pharmaceutical industry, from which he received funding for his research on asthma. The year before he was appointed, he provided an overstated estimation of the efficacy of an asthma drug marketed by the drug company Sepracor. The Food and Drug Administration produced a 'notice of violation' relating to this, and Dr Drazen acknowledged that he had been 'overzealous' in his assessment of the drug (Charatan, 2000, Gottlieb, 2000). Upon taking up the role, Dr Drazen said he would not be editorially involved with any papers relating to asthma or nine major companies from which he had received research funding or consultation fees. This is not, however, in line with the *NEJM*'s stated policy, which says that editors will not have *any* financial relationships with *any* biomedical companies (emphasis my own). Indeed, two years after Dr Drazen's

appointment, the *NEJM* relaxed its COI rules (Gottlieb, 2002). In 2015, further concerns were expressed in an article by two former EICs and a former national correspondent of the *NEJM* (Steinbrook et al., 2015), over a series of articles published that year in the journal, with a supporting editorial by Dr Drazen (Drazen, 2015) (who continues to be editor in chief). These critics were concerned that the articles and editorial suggested that attempts to manage COIs had gone too far (Steinbrook et al., 2015). The *NEJM* is a member of the ICMJE.



Table 6.3: Journals' policies on the management of editors' COIs (High IF are those marked with an asterisk)

Journals	Policy on the management of Editors' COIs (as per the journals' websites)	COIs disclosed on website
<i>NEJM</i> *	<p>'Other members of the editorial staff, if they participate in editorial decisions, must provide editors with a current description of their financial interests (as they might relate to editorial judgments) and disqualify themselves from any decisions where they have a conflict of interest.'</p> <p>'Editors should publish regular disclosure statements about potential conflicts of interests relate d to the commitments of journal staff.' (Davidoff et al., 2001)</p>	No
<i>The Lancet</i> *	<p>'Editors: Should have no direct personal, professional, or financial conflict with any manuscript they might judge, edit, or commission; Shall not use information gained from manuscripts for financial or personal gain; Shall not submit original research to <i>The Lancet</i>; Should not commission from member of current editor's household; Should not accept offers for travel, accommodation, hospitality, or gifts; Submit annual financial disclosure statements to <i>Lancet's</i> Editor.' (James et al., 2004)</p>	No
<i>JAMA</i> *	No comment	No
<i>BMJ</i> *	No comment	Yes

<i>PLoS*</i>	‘Editors are required to declare all relevant competing interests and do not participate in the review of any paper for which they have a competing interest.’ (PLoS Medicine, n.d.-c)	Yes
<i>Annals*</i>	‘Authors, editors, and peer reviewers must state explicitly whether potential conflicts do or do not exist.’  ‘Authors, editors, and peer reviewers must disclose their primary academic and institutional affiliations and all financial relationships that could be viewed as presenting a potential conflict of interest.’ (Annals of Internal Medicine, 2014)	Yes
<i>BMC Medicine*</i>	‘Editors ... are also required to declare any competing interests and will be excluded from the peer review process if a competing interest exists.’ (BMC Medicine, 2016a)	No
<i>CMAJ*</i>	‘Editors who make final decisions about manuscripts must have no personal, professional, or financial involvement in any of the issues they might judge. Other members of the editorial staff, if they participate in editorial decisions, must provide editors with a current description of their financial interests (as they might relate to editorial judgments) and disqualify themselves from any decisions where they have a conflict of interest. Editorial staff must not use the information gained through working with manuscripts for private gain. Editors should publish regular disclosure statements about potential conflicts of interests related to the commitments of journal staff.’ (Davidoff et al., 2001)	Yes

<i>JIM*</i>	No comment	No
<i>Mayo Clinic Proceedings*</i>	No comment	No
<i>AJC</i>	No comment	No
<i>AJM</i>	‘The financial relationship of the editors should be filed with the editorial office and updated annually. The editor should not handle a manuscript if there is a potential conflict of interest. This includes financial interest as well as positive or negative biases toward the author or companies producing materials described in the article.’ (The American Journal of Medicine and n.d.)	Yes
<i>AJOG</i>	‘The financial relationships of the editors should be filed with the editorial office and updated annually. The editor should not handle a manuscript if there is a potential conflict of interest. This includes financial interests as well as positive or negative biases toward the authors or companies producing materials described in the article.’ (of and Obstetrics & Gynecology, n.d.)	Yes
<i>Birth Defects</i>	No comment	No
<i>Clinical Therapeutics</i>	No comment	No
<i>Environmental Technology</i>	No comment	No

<i>IAOEH</i>	No comment	No
<i>JAACAP</i>	No comment	No
<i>JNCI</i>	No comment	No
<i>Risk Analysis</i>	No comment	No

As discussed in Chapter Five, Section 5.4.1, editors of journals operating under the traditional publishing model can also face conflicts due to the fact that the main sources of revenue for such journals' (other than subscriptions) comes from manufacturing sector companies in the form of advertising, supplements and reprints. To mitigate this, and following the principles of transparency and disclosure of conflicts, one interviewee, a medical publishing critic, suggested that journals should:

*'Annually publish a financial statement indicating all of the revenue sources. So, "We sold X number of reprints and made so many millions of dollars; we got so many millions of dollars from advertising; we got so much money from subscriptions." It should be actual numbers of how much they're getting, so people can see where the revenue is coming from.'* (Joel Lexchin)

Disclosing this information publicly would show how much journals rely on revenue from manufacturing sector companies which in turn may influence editors' publishing decisions. Of the professional associations, only COPE and CSE discuss this idea in their guidance, advising that journals should publish the sources and details of journals' income (COPE, 2011, CSE Editorial Policy Committee, 2012). However, Joel Lexchin was sceptical that journals and their owners would agree to make this information public, as it would demonstrate just how reliant they are on revenue from the manufacturing sector:

*'the large American journals, Annals of Internal Medicine and New England Journal of Medicine, and maybe JAMA, just wouldn't declare how much they made from sales of reprints.'* (Joel Lexchin)

None of the websites of the journals in my sample follow this advice and disclose such information.

### **6.3.3 Disclosure of reviewers' conflicts**

The professional publishing associations all say that journals should require that reviewers declare any potential COIs to journals when they ask them to review. Yet while these associations state that there should be systems in place to acquire this information, they do not offer much guidance on what these systems should involve. ICMJE and WAME suggest that reviewers simply be asked, when

approached to do a review. COPE says that if journals provide no guidance, reviewers should proactively inform them of any working or personal relationships with the authors. CSE is a little more helpful: it also states that reviewers should be asked, and further suggests that this question could be incorporated into forms in online submission systems, emails requesting reviews, or simply be included in the journal's policy on its website. As with the guidance on editors' COIs, ISMPP, EMWA and AMWA do not comment on reviewers' disclosure. Again, this is likely because it is not relevant to their audiences. Interviewees from these areas also did not discuss reviewers' COIs.

Analysis of the guidance produced by the publishers in my sample shows that it does not appear to provide effective advice to their journal editors on how to manage the disclosure of reviewers' COIs. The weakness of their guidance is further demonstrated by the fact that the 'contentious cases' journals that are included in my sample lack clear policies on this topic. Wiley offers the most useful guidance, saying that invitations to review should:

'be accompanied by a request for the reviewer to reveal any potential conflicts of interest and a request for the peer reviewer to disqualify or recuse themselves when these are relevant.' (Deakin et al., 2014, p. 10)

*Risk Analysis*, the 'contentious cases' journal in my sample published by Wiley, has only limited ethical guidance, which provides no information on this topic. It was included in my 'contentious cases' sample due to its publication of a peer-reviewed article which did not disclose financial support from the tobacco industry (McDaniel et al., 2005). Elsevier, T&F and Springer have guidance for reviewers, which states that they should make journal editors aware of any potential COIs. However, in these cases, the guidance is in locations where reviewers are unlikely to see it. This information has not been disseminated into the policies of the majority of the 'contentious cases' journals in my sample that are produced by these publishers (*JAACAP, AJC, Clinical Therapeutics, IAOEH* and *Environmental Technology Letters*), where it would probably be of more use (as it is more likely that reviewers would look there). This indicates that it is not currently effectively informing journal editors in the development of their

policies. Likewise, while OUP's 'FAQs for authors' informs readers that reviewers will be asked to decline a review if they have a potential conflict (Oxford University Press, 2013), again, it is unlikely that reviewers would look here, and there is no obvious guidance for editors on how they might develop their policies. *JNCI* – a 'contentious cases' journal (which published ghost-written articles on tobacco (Fields and Chapman, 2003)) published by OUP – does not provide any information on reviewers' disclosures.

All but one of the high IF journals (*Mayo Clinic Proceedings*) in my sample do state in their policies that they require reviewers to disclose COIs (though not all actually provide examples of what such COIs could be – see Chapter Five, Section 5.4.1). Illustrating the rigour of one such journal in this matter, its EIC said:

*'The reviewers are asked when they're invited, they're reminded of it when they get the accept indication to publish, and they're reminded again when they actually submit their review.'* (EIC6)

Yet in contrast, only two of my 'contentious cases' journals discuss reviewers' disclosure in their policies (*AJM* and *AJOG*). An interviewee from a small speciality journal (whose guidance was not part of my sample) said, *'We've never asked that formally from Reviewers. We expect them to be honest.'* (Dianne Dixon, Managing Editor, *International Journal of Radiation Biology*). See Table 6.4 for the journals in my sample that ask reviewers to disclose potential conflicts, with the relevant extract from their guidance.

While the guidance from the publishers and professional publishing associations does generally advise that reviewers disclose potential COIs, their advice on how to do so is not particularly detailed, and a number of the journals in my sample do not state in their guidance that they ask reviewers to disclose. Unless the journals explicitly ask for such information, reviewers may not realise that they need to disclose. From analysis of the journal guidance, there appears to be a considerable amount of variability in their disclosure policies for reviewers, and this was reflected in interviews: editors described various

different processes used to acquire reviewers' COI disclosures, and authors' comments portrayed an often informal system which differs from journal to journal. Thus, while it is, for the most part, acknowledged that reviewers are an actor group who may be conflicted and that this should be managed through disclosure, limited attention is given as to how this should be done. It is also not always clear, from the guidance, what action is taken on the basis of these disclosures: are individuals recused from reviewing, or do editors simply take the disclosures into account when assessing their reviews (as suggested by JAMA's guidance)? The purpose of the reviewers' disclosure is, at times, ambiguous.



Table 6.4: Journals' guidance on reviewers' disclosure of COIs

Journal	High IF or 'contentious cases' journal	Journals' policies on reviewers' disclosure
<i>NEJM</i>	HIF	'Reviewers must disclose to editors any conflicts of interest that could bias their opinions of the manuscript, and they should disqualify themselves from reviewing specific manuscripts if they believe such disqualification would be appropriate ... Reviewers must be asked to state explicitly whether conflicts do or do not exist.' (Davidoff et al., 2001)
<i>The Lancet</i>	HIF	'Decline to review a paper if substantial conflict. Consult with Editor if in doubt. State whether do or do not have conflicts. Describe conflicts on reviewer form if do proceed with review. Editors avoid choosing reviewers from same institution as author or if known collaborator; and consider whether wise to ask known antagonist or supporter. Editors judge whether to use review or seek another.' (James et al., 2004)
<i>JAMA</i>	HIF	'Reviewers may have a conflict of interest in reviewing a manuscript. In general, you should not review a manuscript from a close colleague at your institution. If you have a financial conflict of interest such as owning substantial equity interest in a company that makes a drug tested in the study, please declare that on the form for the editors. This does not preclude an individual from reviewing a paper, but it allows the editor to weigh this information when considering the review.' (Cummings and Rivara Frederick P., 2002)

<i>BMJ</i>	HIF	<p>'You will be asked to give your name and position, and any relevant competing interests, in your report on any article we send you.'</p> <p>'When you provide your review via our online editorial office we will ask you to declare any competing interest that might relate to the article.' (British Medical Journal, 2016c)</p>
<i>PLoS</i>	HIF	<p>'Because it is not possible for all such competing interests to be known by a particular editor, we request that reviewers who recognize a potential competing interest inform the editors or journal staff and recuse themselves if they feel they are unable to offer an impartial review.' (PLoS Medicine, n.d.-d)</p>
<i>Annals</i>	HIF	<p>'Peer reviewers must state explicitly whether potential conflicts do or do not exist.' (Annals of Internal Medicine, 2014)</p>
<i>BMC Medicine</i>	HIF	<p>'Reviewers are asked to declare any competing interests.' (BMC Medicine, 2014b)</p>
<i>CMAJ</i>	HIF	<p>'All participants in the peer review and publication process must disclose all relationships that could be viewed as presenting a potential conflict of interest.' (Davidoff et al., 2001)</p>
<i>JIM</i>	HIF	<p>'We will also ask reviewers to provide a statement of competing interests.' (Journal of Internal Medicine, n.d.)</p>
<i>AJM</i>	CC	<p>'Reviewers must disclose any financial interest they have ... Reviewers should not accept an assignment if they have prior or current relationships with the authors. Reviewers should</p>

		not accept the assignment if there is a competitive relationship with or a negative bias toward the authors.' (The American Journal of Medicine and n.d.)
<i>AJOG</i>	CC	'Reviewers must disclose any financial interest they have ... Reviewers should not accept an assignment if they have prior or current relationships with the authors. Reviewers should not accept the assignment if there is a competitive relationship with or a negative bias toward the authors.' (of and Obstetrics & Gynecology, n.d.)

#### **6.3.4 Disclosure of medical writers' conflicts**

The previous chapter showed that, of the seven professional associations, only EMWA, AMWA and ISMPP refer to the potential COIs of medical writers. EMWA advises that their involvement on a paper should be acknowledged, with their funding sources disclosed; there is no mention of other types of conflicts. However, it also says that they should follow the requirements of the journal (Jacobs and Wager, 2005, ISMPP, n.d., Graf et al., 2009); thus, unless journals explicitly require such disclosures, medical writers do not have to declare such information. AMWA and ISMPP say that COIs should be disclosed (though give no examples of what these could be) (Hamilton and Royer, 2003, Mitrany et al., 2003, ISMPP, n.d.). However (as discussed in Chapter Five, Section 5.5.3), only six journals in my sample – *Annals of Internal Medicine*, *The Lancet*, *BMC Medicine*, *CMAJ*, *AJOG* and *JCP* – refer to the COIs of contributors and/or medical writers, stating that they should be listed in the acknowledgements with their relevant funding (and sometimes other financial disclosures). Two interviewees (Jose Merino (senior editor, the *BMJ*) and Annette Flanagan (executive editor, *JAMA*)) both said that their journals have policies that require the disclosure of medical writers' involvement and their funding sources; however, none of the policy documents available online for these two journals (analysed after the interviews) provide evidence of this.

By asking for the disclosures of contributors/medical writers, the six journals listed above arguably offer more transparency than those that do not. However, what they ask for is often still limited, with only three asking for contributors (specifically also including medical writers) to disclose all potential COIs. The other three ask only for disclosure of contributors'/medical writers' funding sources: this offers some transparency, as it demonstrates whether a manufacturing sector company has paid for their involvement, but these three journals do not require that other COIs be disclosed (see Table 6.5).

Table 6.5: Journal requirements for contributors' disclosure

Journal	Contributor and/or medical writer required to disclose	What should be disclosed
<i>Annals of Internal Medicine</i>	Contributors (specifically including medical writers)	All potential COIs
<i>JCP</i>		
<i>CMAJ</i>	Contributors	
<i>AJOG</i>	Contributors	Funding
<i>BMC Medicine</i>	Medical writers	
<i>The Lancet</i>		

One medical writer (Tom Lang) maintained in an interview that medical writers work strictly with what is provided to them by the authors, and as such they are not in a position to introduce bias into a manuscript. Therefore, he argued, they should not have to disclose COIs. However, as Section 2.4, Chapter Two showed, there is evidence that some medical writers, working on behalf of the pharmaceutical industry, have actually had influence over the development of manuscripts, controlling (to varying degrees) the ways in which articles are structured and the arguments framed (e.g. Ross et al., 2008). As one medical publishing critic, who has been involved in litigation against the pharmaceutical industry, argued in an interview:

*'There are medical writers who we've seen in various scandals who are given the task of manipulating the data, and weren't the least bit concerned about carrying out that function.'* (Leemon McHenry, Medical Publishing Critic)

It is therefore arguably important that they disclose.

## **6.4 How effective is voluntary disclosure in managing conflicts of interest in medical/health journals?**

Section 2.5.1 of Chapter Two offered an overview of the research that has been conducted into the use of voluntary disclosure as a way of managing COIs in various contexts. There are arguments advocating the benefits of disclosure and transparency, such as the fact that it is a low-cost solution, requiring no considerable change (Church and Kuang, 2009, Loewenstein et al., 2012). Critics, however, draw attention to its drawbacks. For example, it relies heavily on the honesty of those disclosing and is not enforceable (Bero, 1999); it may negatively affect the behaviour of those disclosing, causing them to exaggerate the information they give, or behave in a self-serving way (Cain and Detsky, 2008, Cain et al., 2005b, Loewenstein et al., 2012, Jamal, 2012); there are concerns over how disclosure influences the interpretations by recipients of the information (Ben-Shahar and Schneider, 2011, Kassirer, 2009a, Loewenstein et al., 2012, Sah et al., 2013, Jansen and Sulmasy, 2003); and it is difficult to determine exactly what might constitute a potential conflict and therefore what should be disclosed (Jansen and Sulmasy, 2003).

As part of my interview schedule, interviewees were asked for their assessments on voluntary disclosure as a system to manage potential COIs in medical journal publishing. A number of recurrent themes emerged from these interviews regarding disclosure's strengths and weaknesses, as summarised in Box 6.2. In general, interviewees were in favour of the practice of self-disclosure, considering it to be a useful tool in managing COIs. When discussing its weaknesses, they generally focused on problems regarding the practical implementation of it, rather than such issues as those cited above.

*Box 6.2: Summary of interviewees' perceptions of the strengths and weaknesses of voluntary disclosure*

Strengths	Weaknesses
<ul style="list-style-type: none"> <li>• Where disclosures are asked for (including explicit declaration of no COIs if relevant), it forces actors to make a statement or answer questions that are potentially verifiable.</li> <li>• If undertaken, allows recipients of the information to be aware of what may have biased authors and contextualise articles accordingly.</li> <li>• Completing disclosures reminds actors of their inevitable subjectivities and of any bias that can result from this.</li> </ul>	<ul style="list-style-type: none"> <li>• Those disclosing may see it as a pro forma exercise and not take it seriously; those checking disclosures may also see it as a pro forma exercise and not check them thoroughly.</li> <li>• It is difficult to judge one's own conflicts.</li> <li>• Actors may deliberately hide conflicts for fear that readers will attach too much weight to them.</li> <li>• It relies on honesty.</li> <li>• Recipients of disclosures may be unsure of how to interpret disclosures and what weight to attach to them.</li> </ul>

#### **6.4.1 Disclosure's Strengths**

Four interviewees (working in editorial roles) considered that one of the strengths entailed in the completion of disclosure forms or statements (if done honestly) is that it forces actors to actively provide a report about potential conflicts. They felt that most people would honestly disclose potential COIs if specifically requested to do so, particularly if such information is potentially verifiable, as it would be embarrassing and possibly career-damaging if they were found to have lied:

*'You're asking someone to make a statement that is potentially verifiable ... it does work in the sense that the authors are published and there is a statement on record saying what they're competing interests are. Because the world outside can look at that and say, "I know that he's a Jehovah's Witness, so him writing about transfusions, he really should have said that."' (EIC3)*

*'I think it will hurt you more if you don't disclose and then it's found out after, then you're not credible. That would hurt their reputation.'* (Dianne Dixon, Managing Editor, *International Journal of Radiation Biology*)

Thirteen interviewees, from across the interview groups, argued that author disclosures 'empower' (*David Moher, Author*) editors, reviewers and readers, as they allow them to appropriately contextualise articles in terms of what may have influenced and biased those writing them:

*'It's quite important that people see the conflicts of interest at the end of the manuscript so it's fresh in their minds that people have got conflicts, and this is what they are.'* (SE1)

This, however, depends upon these actors seeing the disclosures (see Section 6.3.1). One senior editor from a high IF journal in my sample said that they would weigh up disclosures alongside papers *'and evaluate whether there are any issues surrounding that which either affect publication, or might necessitate you to go round the possible issue of competing issues'* (SE2). Another editor in chief of a journal from my 'contentious cases' sample also said that they would *'scrutinise the articles more carefully for the way they are worded, so that people who do have conflicts of interest are not overstating the significance of the article, or selling anything in the article.'* (EIC4)

Two authors argued that the most important element of disclosure statements is that the very process of completing them reminds actors of their inevitable subjectivities that may affect them and their work:

*'The most important part about the focus on disclosing conflicts of interest is not necessarily that we abide by the letter of the law, but that you keep in mind the spirit of the law: that our work is subject to bias. And that this is a way of reinforcing that all of us need to be cognisant of our biases.'* (A5)

According to these interviewees, through the action of disclosing conflicts, actors are forced to be reflexive and consider how both pecuniary and non-financial relationships may have biased them, or how others may perceive them to have affected their work. However, by completing such disclosures only after the article has been written and submitted, it is not clear how this will benefit the way it has been constructed.



#### **6.4.2 Disclosure's weaknesses**

As Section 6.3.1 argued, disclosures are only useful if editors (and other recipients of them) check them adequately and take action if necessary. However, my data showed that editors rarely have the resources and do not consider it to be their job to check the disclosures of authors and reviewers. Two interviewees argued, therefore, that disclosure is simply seen as a pro forma activity by both those disclosing and those receiving the disclosures, and that it is not adequately checked. While, as discussed in the previous section, two authors interviewed suggested that the process of disclosure forces actors to reflect upon their subjectivities and consider how these may influence their work, two other interviewees countered this by suggesting that it can be difficult to judge one's own conflicts, and that they felt that actors may fail to declare relevant information if they do not consider themselves to be conflicted by it:

*'We can see and observe and judge other people's conflicts, but we can't judge our own.'* (SE2)

*'You can't judge your own competing interests.'* (EIC6)

These interviewees therefore felt that requiring authors (and other actors) to simply provide a disclosure statement is inadequate, and that a form which requires them to actively respond to specific questions would elicit greater disclosure.

However, two interviewees (one senior editor and one author) queried how useful disclosures – both forms and statements – are in practice. They argued that it is difficult for recipients of such information to know how much weight to attach to it, even if detailed amounts and timeframes are given, and that ultimately, one person cannot truly know how much a particular relationship has affected and biased another person:

*'It's hard. You're a reader, so what do you do when you read that the author of the paper owns some stuff, got \$5000 in compensation in the last five years. What does that mean? How do you interpret that? Does that invalidate the study? Probably not, but how do you weigh that up? ... So now*

*you're transparent, but how many grains of salt do you put in when you analyse the results? (Jose Merino, Senior Editor, the BMJ)*

*'What do you do with that information at that point? Do you then discount the article and say "I don't believe it"? Or do you say "Well at least they were up front and I can take it all with a grain of salt." (A7)*

One senior editor (SE2) said that if the interests disclosed are too great, they might reject a paper; however, this (along with concerns over readers disregarding information in their articles) may have an unintended negative effect, with some authors choosing to instead conceal conflicts (see Chapter Seven, Section 7.2.2.1 for more on journals' non-publication policies).

This leads to the main concern about the process of disclosure, which was raised repeatedly by interviewees across the spectrum of actor groups: that it is reliant on the honesty of those disclosing. As they acknowledged, there is no real enforcement mechanism:

*'I have no doubt that if you want to not declare something, there's no really robust thing in place which would stop you from not doing it. So it's mainly integrity that people go by ... ethics and integrity are the things that hold the process in place, it's a very trusting system.'* (A6)

*'If someone wants to lie, they can lie can't they? I mean, what more can you do? How much more can you police people? You've got clear policies in place ... I don't know how much further we really can do, at some point you have to trust the author that they will disclose.'* (Anne Lloyd, Publisher, Elsevier)

As such, perhaps the only way to avoid conflicts impacting on the literature is to avoid involving actors on papers for which they have a potential conflict (see Chapter Seven Section 7.2.2.1) or to try and limit the chances of conflicts occurring, for example through Journal Oversight Committees, or altering the way in which funding is distributed (see Chapter Seven, Sections 7.2.2.3 and 7.3.3). Yet, despite acknowledging some weaknesses, the majority of interviewees focused upon disclosure as being the system through which COIs should be managed, with little focus on other options. The limited number of alternatives put forward are discussed in the following chapter.

## 6.5 Concluding discussion

Through an analysis of the data (both policies and guidance, and interviews), this chapter examined how COIs are primarily managed in medical journal publishing. This data showed that voluntary disclosure has become embedded within the institutional environment of medical journal publishing, and is considered to be the primary tool – the ‘norm’ – through which to manage COIs, with limited discussion of alternative methods (those additional systems that do exist are discussed in Section 7.2 of Chapter Seven). Actors’ understanding of what COIs are (as discussed in Chapter Five) and how they should be managed – what Schmidt calls their ‘background ideational abilities’ – allows this status quo to persist.

The chapter examined which actor groups have their potential COIs managed through disclosure, and which do not (and which, therefore, possibly remain unmanaged). As with Chapter Five, which demonstrated the ways in which authors’ COIs are emphasised while other actor groups are omitted from the discussion, this chapter showed that author disclosures were fairly ubiquitous in medical journal publishing. Further, what and how actors are required to disclose, together with what is done with those disclosures, varies across publications: there is no standard, journal-wide policy.

While disclosure is now commonly required of authors, this is less the case for other actor groups, such as editors, journal owners, peer reviewers and contributors (such as medical writers). While the professional associations do advise that journals request disclosures from editors and reviewers, there is limited guidance on how this information should be obtained, and as this chapter has shown, few journals publicly disclose their policies on these actors, nor do many publish editors’ COIs. While the professional associations aimed at medical writers advise in their guidance/policies on the acknowledgement of contributors such as medical writers, they say that the journals’ policies should be followed. Yet such actors are noticeably absent from many of the journals’

disclosure requirements. As these take precedence, it consequently means that these actors' conflicts may remain hidden.

Despite the fact that the professional associations do advise on the disclosure of editors' COIs, this does not appear to have trickled down to the majority of publishers and journals. This indicates, perhaps, that the professional associations are not fully utilised, and would benefit from greater promotion to their constituencies. However, even some of those journals whose editors are members of these organisations do not follow their guidance in this regard. The attempts by the professional associations regarding reviewers' disclosures appear to be tokenistic; despite advising that they disclose, the associations do not offer much practical advice on how journals could effectively solicit this information (and as such, journal requirements appear to be variable in this regard). Requirements for disclosures by medical writers and other contributors are frequently absent; given the issues that have occurred with this group of actors, this is perhaps surprising (Bastian, 2006, Lagnado, 2002, Ross et al., 2008, McHenry, 2010). This calls into question the purpose of the professional associations and their guidance, with three medical publishing critics suggesting that they exist merely to give the impression of taking such matters seriously, while in reality they are not as effective as they could be.

The requirements for authors' disclosures vary across journals, both in terms of what they should disclose, and how they should do so. Journal editors appear to have autonomy in terms of setting their policies, and analysis shows that they are not always as stringent as recommended by their publishers. There may therefore be benefits to be drawn from publishers being more insistent on particular practices being followed as part of the condition for publication (and in the case of publishers such as Springer, OUP and T&F, they should actually provide more detailed guidance). It would also help if the owners (publishers or societies) provided more resources both in terms of educating actors and in enabling editors to more thoroughly check disclosures from authors. This should not be limited to biomedical journals as COIs can affect journals in any discipline:

publishers should therefore ensure that all of their journals have robust policies in place.

More uniformity, both in terms of what actors are asked to disclose and the format in which they are asked to provide it, would also make the process easier: authors complained about having to fulfil different requirements for each journal they submitted to. The ICMJE form goes some way towards doing this for authors, but it has not been uniformly adopted across medical journals. Further, as argued by a number of interviewees, this form is somewhat cumbersome, unwieldy and too detailed; this has put a number of journals off using it. However, while the ICMJE form is criticised in this regard, other interviewees complained about a lack of detail provided in disclosures. Requiring disclosure forms from authors, rather than simply asking them to provide statements, may force them to disclose information they may not otherwise consider to constitute a bias; the same practice could perhaps be applied to other actor groups, such as editors and reviewers. While the information on forms from authors could not necessarily all be reproduced directly onto articles, in the interests of transparency it should be publicly available so that readers are better able to contextualise information according to any relevant conflicts. Therefore, ideally the in-article statements should work in conjunction with more detailed forms, such as the ICMJE's, or a database such as ORCID (see Chapter Seven, Section 7.3.1, for more on this), which readers could access if they so wished.

While the previous chapter showed that conflicts can arise from both financial and non-financial relationships, it demonstrated an emphasis in medical journal publishing on the former, and as such this is focused on in the disclosure requirements. This is perhaps because they are easier to define and quantify; however, as discussed in Chapter Five, non-financial interests can also be problematic if they present conflicts. There perhaps therefore needs to be more education to raise awareness of how non-financial conflicts can affect individuals.

Despite the heavy focus placed on the process of voluntary disclosure to manage COIs, some interviewees did acknowledge weaknesses with the process, although they found it difficult to conceive of alternative solutions. It appears to often be a pro forma exercise, with it being unclear who the disclosures are being made to, or how this information will subsequently be used. Disclosure also relies on self-awareness: people have to realise their own conflicts and potential to succumb to them. However, these processes are often unconscious and unintentional (Moore et al., 2005). The failure to disclose may therefore be unintentional, and this highlights one of the problems with relying on self-disclosure. More education is perhaps required for those engaged in medical/health research on how they can be conflicted, and how those conflicts can (perhaps unconsciously) affect their research and articles.

While there are clear weaknesses with the process of disclosure, there are also arguably some benefits. For example, it encourages actors to be reflexive and consider how relationships, both pecuniary and other, may have informed their research and analysis. However, in the case of authors, it is not clear what the impact of doing this after an article has been written will be. It might be better to bring consideration of COIs to the forefront of authors' thinking when actually conducting the research and writing the article. This could be achieved, for example, by requiring them to include a reflexive disclosure section within their methodologies in research articles (such sections could also be included in editorials, reviews and so on).

In summary, this chapter shows that disclosure has become established and accepted as the norm for dealing with COIs in medical journal publishing, and that this process is in general applied to only a limited group of actors, resulting in the possibility of conflicts that could impact on the content of journals remaining unmanaged. My findings suggest that this is generally accepted by those within the medical journal publishing industry without question, and with a limited ability to consider other, wider options, which may more effectively prevent COIs from adversely affecting the medical journal literature. I argue that,

rather than simply accepting this system as being the only way to manage COIs, questions should be asked as to why it has been portrayed as such, and by whom; this might allow alternative solutions to be developed. The following chapter looks both at existing mechanisms for managing COIs beyond disclosure, to examine their role in practice, as well as at suggestions of alternatives made by (a minority) of interviewees – primarily medical publishing critics – of more fundamental changes to the system of medical research and publishing.

## **CHAPTER SEVEN: RESULTS**

# **Beyond Disclosure: Examining the Efficacy of Additional Mechanisms to Manage Conflicts of Interest and Bias in Medical Journal Publishing**

### **7.1 Introduction to the chapter**

The previous chapter explored how disclosure is portrayed in publishing policies and guidance as being the primary means of managing actors' COIs in medical journal publishing. It highlighted some of the weaknesses inherent in the process, demonstrating that it is perhaps not sufficient, on its own, to adequately manage conflicts. While disclosure is clearly presented in the data as the main method for managing COIs, this chapter explores the extent to which additional broader mechanisms were evident in the sample guidance/policies and interviews, that may also assist in the management of COIs. When asked about new ideas for how the management of COIs could be improved, responses from those working directly within the medical journal publishing industry were limited. They mainly built on the concept of disclosure. However, two alternative suggestions were raised (as will be discussed in Section 7.3), primarily by medical publishing critics. This demonstrates that change in thinking around COIs is perhaps possible. This chapter begins, in Section 7.2, by analysing the sample documents and interviews to identify those existing broader mechanisms, firstly looking at those that assist with managing COIs in research, before looking at those that help with handling them in journals. It examines their uptake in practice, as well as how effective they are perceived to be in reality. The chapter continues, in Section 7.3, by considering ideas for other ways of managing COIs – alternatives put forward by a small number of interviewees.



## **7.2 Mechanisms beyond disclosure that assist in the management of conflicts of interest**

As Chapter Six showed, in medical/health journal publishing, disclosure is portrayed as being the primary mechanism through which COIs are managed. As part of my interview schedule, participants were asked whether they felt there were any existing additional systems beyond disclosure to assist in managing COIs. The following section explores their responses. Several supplementary mechanisms and policies were identified. Along with exploring interviewees' discussion of these, this section also analyses my sample policies and guidance, to understand how much of a role they appear to play in managing COIs in practice. When asked about what methods exist beyond disclosure to help manage COIs, interviewees frequently identified several that were specific to clinical research: Clinical Trial Registration (CTR), Clinical Trial Protocols (CTPs) and Reporting Guidelines. This highlights the focus placed on this particular type of research within medical/health journal publishing as being the primary type at risk of being affected by COIs.

### ***7.2.1 Further mechanisms to manage conflicts of interest in research***

#### ***7.2.1.1 Clinical Trial Registration***

Interviewees identified Clinical Trial Registration (CTR) as a mechanism that helps to mitigate selective reporting and publication bias, with one of its purposes being to 'prevent selective publication and selective reporting of research outcomes' (ICMJE, 2014b). The ICMJE declared in 2004 that member journals would no longer publish trials if they had not been registered on a public registry that participates in the WHO International Clinical Trials Registry Platform (Council of Science Editors, 2012b, De Angelis et al., 2004), and encouraged other journals to follow suit (see De Angelis et al., 2004). Registering clinical trials when they commence on a publicly available database reduces the chance of publication bias occurring, by allowing editors to check that the results have not been published more than once, thereby preventing a false impression arising

that there is more evidence supporting a particular claim than there is in reality (De Angelis et al., 2004, Ross et al., 2012, Simes, 1986) (see Section 3.3, Chapter Two, for more on publication bias).

CTR is endorsed by all the professional publishing associations in my sample. CSE backs the ICMJE's position (CSE Editorial Policy Committee, 2006) and WAME likewise supports CTR, arguing that 'When suitable registries are available, editors should require prior registration of all trials published in their journals.' (WAME Editorial Policy Committee, 2005b) ISMPP's GPP2 states that:

'Research sponsors must register and post all applicable clinical trials according to the definitions and timelines required of them by relevant legislation and guidance' (Graf et al., 2009).

COPE also advises that best practice procedures for editors include requiring clinical trials to be registered in order to prevent publication bias (COPE, 2011). Interviewees who discussed CTR (editors, authors and medical writers) generally spoke positively of it. One interviewee suggested that more could be done with CTR in managing publication bias: for example, it has the potential to prevent the suppression of unfavourable results, by exposing investigators and sponsors who have not published trials that they have registered:

*'You could imagine registries doing a much better job of shaming investigators or sponsors who haven't published their research. They have a reasonably unbiased dataset of trials that are planned or already started ... It could use an automated mechanism, just throw up on its homepage who's in the doghouse this week for having done last year 50 trials and not having published them!'* (SE2)

S/he felt that this could be a way to put pressure on researchers to publish all of their trials, including those with negative results; however, editors may still be reluctant to publish such studies.

Despite the endorsement of CTR by the professional publishing associations in my sample, only one of the publishers whose policies I looked at (Wiley) mentions it, recommending that:

‘Medical journals that publish clinical trials should make prospective registration a requirement for publication of such trials.’ (Deakin et al., 2014, p. 6).

While Elsevier signed up to the AllTrials Campaign on the 23<sup>rd</sup> June 2014 (Lane, 2014) – which calls for all past and present clinical trials to be registered, together with the reporting of their results – there does not appear to be any mention of it in the guidance and policies available on its website for either authors or editors. At the time the analysis for this project was conducted, Springer, OUP and T&F also did not refer to CTR in their guidance for authors or editors. While the journals in my high impact factor (IF) sample do all provide information on CTR, and require that the clinical trials that they publish be registered, four of the journals in my ‘contentious cases’ sample, which do publish clinical trials, do not discuss trial registration in their guidance for authors, and nor do they ask for the trial registry number during the submission process. See Tables 7.1 and 7.2 for a list of my sample journals and whether they do or do not refer to CTR in their guidance and/or submission processes.

Table 7.1: Reference to CTR in the guidance and/or submission processes of the High IF journals

Journal	Publishes Clinical Trials	Refers to CTR in guidance and/or submission processes
<i>NEJM</i>	Y	Y
<i>The Lancet</i>	Y	Y
<i>JAMA</i>	Y	Y
<i>BMJ</i>	Y	Y
<i>PLoS Medicine</i>	Y	Y
<i>Annals</i>	Y	Y
<i>BMC Medicine</i>	Y	Y
<i>CMAJ</i>	Y	Y
<i>JIM</i>	Y	N
<i>Mayo Clinic Proceedings</i>	Y	Y
<b>TOTAL THAT REFERENCE CTR</b>	<b>10</b>	<b>9</b>

Table 7.2: Reference to CTR in the guidance and/or submission processes of the contentious cases journals

Journal	Publishes Clinical Trials	Refers to CTR in guidance and/or submission processes
<i>JNCI</i>	Y	N
<i>JAACAP</i>	Y	Y
<i>JCP</i>	Y	Y
<i>AJC</i>	Y	N
<i>AJM</i>	Y	N
<i>AJOG</i>	Y	Y
<i>Risk Analysis</i>	N	N/A
<i>Clinical Therapeutics</i>	Y	Y
<i>IAOEH</i>	N	N/A
<i>Environmental Technology</i>	N	N/A
<i>Birth Defects</i>	Y	N
<b>TOTAL THAT REFERENCE CTR</b>	8	4

While interviewees were supportive of CTR, a number expressed concern regarding the lack of enforcement of it by journals:

*'At the moment, journals don't even seem to be bothered to check if a trial's registered or not.'* (Liz Wager, Medical Writer)

*'If journals really wanted to respond appropriately to this ... they would have to enforce ICMJE criteria about registration of clinical trials ... even the journals that belong to that association haven't uniformly enforced the criteria.'* (Joel Lexchin, Medical Publishing Critic)

This finding was supported by a 2013 study, which found that of 200 medical journals that published clinical trials, only 28 per cent required CTR (Wager and Williams, 2013). Thus, while CTR is generally seen, theoretically, as a positive

initiative in helping to prevent COIs and resulting bias from affecting the published literature on clinical trials, it would appear that there has not been a comprehensive uptake of it by the medical publishing industry; until there is, CTR's potential effectiveness in this regard will be difficult to assess.

#### *7.2.1.2 Clinical Trial Protocols*

Interviewees referred to the development of Clinical Trial Protocols (CTPs) as another initiative that has the potential, where used, to help prevent bias from affecting the conduct of clinical trials, and consequently the medical journal literature. Drawn up at the commencement of a clinical trial, the protocol document provides details of how the trial will be conducted, including its objectives, design, methodology, statistical considerations and organisation (UK Government, 2004). When articles are submitted for publication, journals can thus compare discussion of the completed research against the CTP, in order to check that no changes (such as altered end-points) resulting from any bias on the part of the study authors, have been made (Altman and Moher, 2013, Moher et al., 2010). CTPs thus improve accountability by ensuring that researchers keep to their original research designs:

*'It helps commit people in advance to what they're gonna do, before they actually do it ... It means people are gonna be held accountable for what they thought their sample size was, what they thought their primary outcome was, what they were going to do.'* (A4)

If there are *'discrepancies between the protocol and the final results, they ought to be explained'* (David Moher, Author). CTPs allow editors to check for any *'massaging and spinning which can move towards a more beneficial picture'* (SE2). The SPIRIT Statement assists with the development of CTPs, with the aim of improving their quality, by providing *'recommendations for a minimum set of scientific, ethical, and administrative elements that should be addressed in a clinical protocol'* (SPIRIT Statement, 2014).

However, none of my sample publishers' guidance refers to CTPs. From my journal sample, only *Annals*, *The Lancet*, *JAMA*, the *BMJ* and *PLoS Medicine*

specifically state that CTPs should be supplied. *NEJM* merely requires that a statement be included that confirms that the protocol was approved by the relevant ethics committee; *BMC Medicine* encourages CTPs to be published where possible (but does not state that they need to be submitted with the manuscript); and *JNCI* says that CTPs should be provided as supplementary data for publishing online wherever possible. The other journals in my sample do not mention trial protocols at all. None of my sample guidance and policies refer to the SPIRIT Statement.

Perhaps reflecting this, none of the interviewees who discussed trial protocols as a means of managing bias were from either my 'contentious cases' journal sample, or from other small, speciality journals. Those that did discuss trial protocols were from the high IF journals, medical publishing critics, and others who work in publication ethics, and who were therefore likely to have an awareness of such initiatives. As such, while CTPs may have the potential to assist in managing bias in the reports of clinical trials, the insistence by journals that authors provide them appears to be limited.

#### *7.2.1.3 Reporting guidelines*

Reporting guidelines have been developed to 'alleviate the problems arising from inadequate reporting of randomized controlled trials' (CONSORT Statement, n.d.). They provide checklists and flowcharts that set out the requisite items authors should provide to journals. Their aim is to enable people to perform research robustly from the start of the process through to publication:

*'They are primarily trying to get people to do research in the right way, from the start of the process, not just the writing up of the research, but right through from the design of the experiments, the protocols, the way they recruit subjects, to get that whole process correct. ... Another aim is to get transparency and openness.'* (P1)

Through doing so, they are also intended to help in the management of bias, by assisting researchers in providing a transparent account of the conduct and findings of a study. There are 319 guidelines available on the EQUATOR Network

(EQUATOR Network, n.d.-a), an umbrella organisation that seeks to improve the quality of research and resulting publications (EQUATOR Network, n.d.-b). These guidelines offer advice on a vast array of different types of research studies (EQUATOR Network, n.d.-c). The main guidelines are listed in Table 7.3.

*Table 7.3: Reporting guidelines for main study types. (Adapted from EQUATOR Network, n.d.-a)*

<b>Type of trial</b>	<b>Reporting guideline</b>
Randomised Trials	CONSORT
Observational Studies	STROBE
Systematic Reviews	PRISMA
Case Reports	CARE
Qualitative Research	SRQR
Diagnostic/Prognostic Studies	STARD
Quality Improvement Studies	SQUIRE
Economic Evaluations	CHEERS
Animal Pre-Clinical Studies	ARRIVE
Study Protocols	SPIRIT

Nineteen interviewees (publishers, managing and senior editors from high IF journals, authors and medical writers) referred to reporting guidelines, saying that they are useful tools and that they improve the reporting of research:

*'I think they actually make people's lives easier, reporting guidelines certainly. CONSORT is a really, I think it's a good, it benefits researchers, because it enables them to structure their research in a systematic way ... And the fact is that people who research also read other people's work, so if you make sure things are reported in that, you know, properly structured, transparently reported way, it benefits everyone.'* (SE4)

None of the interviewees from my 'contentious cases' journals, however, discussed them. As with CTR, there is limited reference to reporting guidelines in the sample publishers' guidance: only Wiley refers to the EQUATOR network (an umbrella organisation that brings together key actors in medical research and publishing who have been involved in the development of such guidance) in



its section on 'Reporting Guidelines' (Deakin et al., 2014, p. 7). Eight of my sample journals – all from my 'contentious cases' sample – do not discuss them in their guidance or submission processes (*AJC, AJM, Birth Defects, Environmental Technology, IAEOH, JNCI, JIM and Risk Analysis*). As one publisher acknowledged:

*'the reporting guidelines like CONSORT, I don't know how often they're really used properly, and I'm sure that they could be used better.'* (Chris Graf, Publisher, Wiley)

According to one interviewee who was involved in the development of CONSORT and PRISMA, there is actually an over-abundance of reporting guidelines, and publishers and editors may consequently be confused as to which to endorse:

*'the issue is, are those guidelines all created equal, or are some good and some not so good? And that would be important to editors, because they may want to know, they may want to say "I think we ought to endorse these, they seem well developed, they've been evaluated, whereas others are not so good, and maybe we don't want to encourage our authors to use them."'* (David Moher, Author)

Further, while those interviewees who discussed the reporting guidelines did speak positively of their intentions, two expressed concerns about their practicality. One managing editor argued that, while he felt initiatives such as CONSORT were, in theory, a good idea, in reality they simply present journal offices with more work: another item for them to try and get authors to deliver. When journals are under pressure to get articles published (and particularly for small, under-resourced publications who do not have the time to chase authors), they may be unable to wait until authors have provided them with such supplementary documents. Further, in fields where there are a number of competing journals, authors may opt to submit to the ones which have the least requirements:

*'You've thought up the most amazing document [CONSORT], but you didn't give any thought to my constituency. How the hell are we gonna apply that to the real world and get this information, and then get articles published? There's no way I'm gonna go out and enforce it, because I can't.'* (ME2)

As is clear from the above quotation, this interviewee felt that, while initiatives such as CONSORT were in theory a good idea, in practice they do not have the

resources available to try and get authors to produce this information on top of everything else required. Overall editors gave the impression of being over-stretched resource-wise, and as such may also not have time to enforce such policies. Editors may request that authors provide the checklists, but this comment indicates that they (particularly those whose journals are less well resourced) may not feel able to enforce it (for example, by chasing the authors up and/or refusing to publish articles where such documents are not provided). As another interviewee pointed out, from their experience, some journals that have signed up to CONSORT still do not always insist on all the requisite components being included:

*'Even journals that require the CONSORT statement will publish randomised trials that don't have all of the CONSORT elements in them.'* (Tom Lang, Medical Writer)

Thus, while reporting guidelines may in theory be a useful initiative, their practicability, and therefore effectiveness, has been questioned. David Moher suggested that institutions should employ 'publications' officers' who are responsible for *'ensuring that authors have some sort of training, they are aware of reporting guidelines and all of these issues'*, in order that they will be aware of what they need to provide journals with.

## **7.2.2 Further mechanisms to manage conflicts of interest in journals**

### **7.2.2.1 Non-publication policies**

Five interviewees suggested that certain types of articles, such as editorials, commentaries and reviews, could potentially be at a greater risk of bias than others. Six journals from my sample – five high IF journals (the *BMJ*, *NEJM*, *The Lancet*, *PLoS Medicine* and *Annals*) and one 'contentious cases' journal (*AJM*) – state that they will not publish particular types of article (such as those listed above) if the authors have conflicts (see Appendix VII); this, of course, depends upon authors' honest disclosure of conflicts. These interviewees explained that editorials, commentaries and narrative review articles are more subjective, and therefore at risk of being influenced by COIs *'Every opinion piece is an opinion, so it's going to be biased'* (Chris Proctor, tobacco company (BAT) representative).

Original research articles, two editors in chief argued, contain trial protocols (see Section 7.2.1.2) and methodology sections which enable them to be judged objectively; while COIs remain an important consideration, these act as safeguards against them:

*'In research you've got at least a fighting chance of picking up on bias ... But when someone's sending me an opinion piece, you're a lot more vulnerable ... The more it's an editorial or opinion piece, the more I'm worried that it's someone grinding an axe. Is somebody really putting a well-glossed article out which is actually just promoting their own personal agenda or their own beliefs?'* (EIC3)

One editor in chief (EIC1) of a high IF journal said that they would reject such articles if written by 'industry', unless they were specifically looking for an industry perspective. Another EIC of a high IF journal (EIC6) said that they would not publish such articles if the author had any competing interests; similarly, a senior editor from another high IF journal (SE1) said that they would not commission letters or reviews from anyone who they knew to have a conflict, and would retract them if they were found to after publication.

Interviewees, however, cited potential problems that may arise from a refusal to publish particular types of articles from authors with conflicts. Firstly, it was argued that if authors are worried that their articles will not be published, it may lead them to hide their conflicts. Secondly, six interviewees argued that actively refusing to publish research that has been properly conducted, simply on the basis of its authors having conflicts which they have disclosed, is itself an unethical practice. Thirdly, a concern was expressed that journals may experience a shortage of authors if they refuse to publish those with conflicts: *'Everybody's done some consulting or got a grant ... You can't exclude those people, or then you won't have any authors.'* (Jose Merino, Senior Editor, the *BMJ*). Indeed, the *NEJM* attempted a policy in the 1990s whereby they would not publish any editorials or review articles from authors with *any* financial conflicts; however, citing a lack of authors who fulfilled this criteria, they altered the requirement to 'any *significant* financial interest' (emphasis my own) (Elliott, 2008). Finally, if journals make it clear that these are opinion pieces and are therefore subjective,

then readers should be able to assess them on that basis: one editor in chief (EIC3) argued that one of the purposes of journals is to provide a forum for debate, and different perspectives should be allowed to be put forward in that context.

Some journals have instigated policies whereby they refuse to publish articles resulting from research funded by the tobacco industry. The *American Journal of Respiratory Cell and Molecular Biology* and *American Journal of Respiratory and Critical Care Medicine* have not published tobacco-funded research since 1995 (Frankel, 1995) and their stance is clearly stated in their 'Instructions for Contributors' (American Journal of Respiratory and Critical Care Medicine, 2016, American Journal of Respiratory Cell and Molecular Biology, 2016). *Tobacco Control*, published by the BMJ Group, originally stated that it would not ban such articles as doing so would prevent 'the occasional honest paper' being published (Chapman, 2005); however, it changed its position in 2013 (Malone, 2013) and is now also unequivocal in its stance on tobacco-funded research:

*'Tobacco Control will not consider for publication papers reporting work funded, in whole or in part, by a tobacco company or tobacco industry organization. Nor will the journal consider papers by authors who accept tobacco industry funding, including funding for research costs, for all or part of any author's salary, or other forms of personal remuneration.'* (Tobacco Control, 2016)

In explaining the development of such practices, one former EIC for such a journal, interviewed in the capacity of a medical publishing critic, explained:

*'The evidence accumulated that there was so much going on behind the scenes at some of these tobacco-related publications, that we could never actually trust what was in the article, because there were lawyers being hired to write things that weren't disclosed, there was all sorts of data manipulation, there were legitimate academic authors who were removed and had their data published without their knowledge. So there were just so many examples of articles getting published that you really couldn't trust ... As that accumulated, some journals just said, "No matter what, we don't even know the right questions to ask, this could just be so biased."'* (MPC3)

From my sample, only *PLoS Medicine* and the *BMJ* (both high IF journals) have adopted such a policy: *PLoS Medicine* in 2010 (PLoS Medicine Editors, 2010) and the *BMJ* in 2013 (Godlee et al., 2013). Of the journals in my 'contentious cases' sample, selected due to their publication of contentious tobacco-funded research (*Risk Analysis*, *JNCI*, *Environmental Technology*, *Birth Defects* and *IAOEH*), none have any such published policies. Interviewees from the tobacco industry, perhaps unsurprisingly, expressed concerns about such policies, arguing that refusing to publish research simply on the basis of its funding origins is unethical:

*It's somewhat unethical to be able to get volunteers into a study if actually the results of the study are never going to appear in public.'* (Chris Proctor, Chief Scientific Officer, BAT)

*'I think they should publish everything. That's the simple thing. If the data is good and it's making a good new point, the data is sound, it's well argued and the discussion isn't biased, then what's wrong with it?'* (Peter Lee, a long-term consultant for the tobacco industry, who has authored articles for the tobacco industry)

This stance on tobacco-funded research has led to debates about whether such a policy should be extended to the pharmaceutical industry (e.g. Smith et al., 2014). However, the participants I interviewed who work within publishing were resoundingly against the idea, querying both the ethics and practicalities of it. They argued that the pharmaceutical industry is the only sector that can afford to fund certain research, particularly in niche areas; and claimed that, without it, research in some small, speciality fields would probably not be carried out. Most interviewees argued that, despite the problems inherent in research funded by the pharmaceutical industry, this work still needs to be done:

*'Pharma can have bad press, but at the same time they're producing the drugs that are saving the lives.'* (Ann Lloyd, Publisher, Elsevier)

In a similar vein to the arguments made above in relation to tobacco funded research by Chris Proctor and Peter Lee, another four interviewees (a publisher, two senior editors, and a managing editor) also expressed concerns over whether it is ethically right to implement policies that actively suppress research:

*'The study's already happened. The participants have taken part in the study, it's actually data. There's sort of an ethical argument for saying that if people have taken part in medical research, you can't then suppress it.'* (SE2)

Two interviewees from those journals that have banned tobacco-funded research argued that while tobacco has no positive health values attached to it, medicines can be both necessary and beneficial:

*'There's no justifiable value [research funded by the tobacco industry] ... pharmaceutical treatments do generally help people. Pharma is trying to generate drugs which at the end of the day hopefully will help to treat disease, have some benefit ... Whereas tobacco, there is no laudable goal.'* (SE2)

None of the journals in my sample refuse to publish research funded by the pharmaceutical industry. However, one interviewee, Richard Smith (former editor in chief of the *BMJ*), did not feel that the tobacco and pharmaceutical industries should be approached differently. He contended that it is illogical to ban tobacco-sponsored research on the basis that it has manipulated studies and articles, while still publishing research produced by the pharmaceutical industry. This is because it has been shown that some pharmaceutical companies have employed many similar methods as the former to hide bias, both through controlling the research and resulting publications

*'If you're going to follow the line of not publishing tobacco-funded research because a) there's lots of evidence of it being corrupted and b) there was evidence of tobacco companies continuing using this as a way to ignore negative aspects of tobacco or continuing to publish things that can be positively harmful. Then all of that applies to drug companies on a much bigger scale.'* (Richard Smith, former EIC of the *BMJ*)

Smith instead supports the publication of all research, regardless of its funding source, providing there are effective mechanisms in place to manage bias in both the research and resulting publications. Another interviewee (a medical publishing critic who was previously a senior editor of a journal that has banned tobacco-funded research), did not agree. S/he argued that the pharmaceutical industry has responded more positively to criticisms than its tobacco counterparts, and that such a ban should therefore not be applied to research funded by the pharmaceutical industry:

*'Drug research has really responded a lot better than tobacco research. The tobacco industry didn't start saying they were going to disclose things more, or try to put in all these safeguards. In the drug study world, there have been a lot of changes in the way drug studies are reported and what has to be disclosed.'* (MPC3)

#### 7.2.2.2 Peer review

When asked about systems in place that can help to manage COIs, besides disclosure, 12 interviewees (editors and publishers) discussed peer review. These interviewees suggested several ways in which reviewers could assist in preventing COIs from having an impact on articles. Firstly, they are able to check that the methods cited are suitable and that the conclusions accurately reflect the data available; this, however, is dependent on the data being accessible to reviewers, and their being able to analyse it. Secondly, they can assess articles for bias in the context of any disclosed conflicts; this, however, is only possible if authors are named and have honestly declared any conflicts, and that this information is provided to the reviewers (as shown in Chapter Six, from analysis of journal policies, it is not clear that this is done). Thirdly, reviewers can alert editors to undisclosed conflicts; however, this is again dependent on authors being named, and it would be a question as to whether reviewers were aware of them. However, in their publicly available guidance for reviewers, none of my sample journals provide advice for reviewers on assessing articles for bias; nor do my sample publishers, or professional associations.

Concerns were expressed by interviewees over how robust peer review as a process is. One managing editor acknowledged that, *'it's a flawed system'*, and that it is, *'only as strong as your weakest link'* (Elizabeth Moylan, *BMC Medicine*). An author complained that reviewers are not properly trained, and further, that as reviewers are not paid, they cannot be relied on to definitely do a thorough job: *'the whole peer review is free of charge. Well, you get what you pay for!'* (David Moher). This raises the question, therefore, of how much peer review can be relied upon to help manage conflicts. While journals with a high IF, which have greater resources than their lower IF counterparts, may be able to attract good

quality reviewers, as well as being able to pay for statistical reviewers who are specifically trained to thoroughly check the data that is made available, this is not necessarily the case with smaller, speciality publications. According to one managing editor, referring to their experiences of working on such journals, *'it's very easy to just push things through peer review.'* (ME2)<sup>23</sup> Chris Proctor from BAT argued in an interview that:

*'I think if tobacco companies and other commercial enterprises are to publish research, it should put the journals on high alert to really review the papers properly and ensure that anything that's concluded from the data can be concluded from that data; it's not stretching that data in a further way. That is what peer review is supposed to be about. Maybe when you've got commercial interests involved, you just need to make sure that scrutiny is turned up to its highest level.'*

This, however, depends on the involvement of such 'commercial enterprises' being declared. Further, raw datasets (particularly from large clinical trials) are often not made publicly available (see Section 7.3.2 of this chapter for more on this). In such cases, peer reviewers would not be able to truly check whether reported results accurately reflected the data; as a senior editor for a high IF journal in my sample said in an interview:

*'We don't get the data for peer review.'* (SE4)

Four interviewees raised this as being a problem with peer review. Even if the data are made available, reviewers will not necessarily have the expertise to analyse them; journals therefore need to have the resources to employ professional statisticians to review them (although as discussed in Chapter Five, Section 5.4.3, *JAMA*, which did previously do this, reversed its policy due to the fact that, according to an interviewee from the journal, they were losing commercially-sponsored papers).

Ten interviewees suggested that the scientific community – those reading the published articles – can themselves act as peer reviewers of published papers,

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<sup>23</sup> This senior editor did consent to be named; however, given the forthright nature of this comment, I have chosen to anonymise the individual to protect their identity.



and may identify and contact journals about undisclosed conflicts. However, even if undisclosed conflicts are detected, and an amendment or retraction issued, the article in question will still have been in the public domain for a period of time, and may itself have been cited. COPE has developed two flowcharts that describe the processes journals should follow if either reviewers or readers contact them in relation to undisclosed conflicts (Wager, 2013a, Wager, 2013b). In both cases, however, the charts advise that if authors deny a claim, the journal should simply proceed with the publication. If journals follow this advice and simply accept authors' denials, this brings into question the extent that both pre- and post-publication peer review can be relied on as a system to manage COIs. That said, as discussed in Chapter Six, Section 6.4.1, four interviewees felt that the fear of being caught out by the scientific community, and the resulting embarrassment, may alone motivate authors to behave honestly and disclose. Five senior/managing editors said that they had experiences of readers getting in touch when they spotted undisclosed conflicts, but they acknowledged that this happens rarely. A long-term consultant for the tobacco industry, who has authored articles for it (Peter Lee) hypothesised that this may be because readers are fearful of '*rocking the boat*' and being '*accused of libel or slander*'. Another author said that unless he spotted a '*horrendously egregious*' omission, he would probably just dismiss the article; he would not '*pick up the phone and call the journal or society*' (A6). He agreed with Peter Lee's suggestion that readers might be reluctant to report problems with articles: '*the whistle-blower doesn't look too good probably!*' None of the journals in my sample currently offer information to readers on what to do if they know or suspect there to be undisclosed conflicts.

### 7.2.2.3 Journal Oversight Committees and editors' contracts

Chapter Two, Section 2.3.1.2 gave an overview of past incidents where editors in chief at *Annals of Internal Medicine*, *JAMA*, *CMAJ* and *NEJM* had been fired by their journals' owners (Willinsky et al., 2007, Young, 2009, Tsai, 2003, Charatan, 2000, Hoey, 2006). Chapter Five, Section 5.2.2 discussed the COIs that EICs and journal owners can face and raised the notion of editorial freedom. Some journals have consequently set up Journal Oversight Committees (JOCs) to manage these

conflicts. However, while JOCs are designed to offer editors protection by safeguarding editorial freedom, the number of journals in my sample that have them is limited: only *JAMA* has one (established after the dismissal of George Lundberg as EIC in 1999 due to a conflict between him and his journal's owners, the American Medical Association (Tsai, 2003)), while *CMAJ*, which had one in place (established in 2002) when the analysis for this thesis was primarily conducted, discontinued it in 2016. The journal's website does not explain why, stating only that the Canadian Medical Association's (CMA) board of directors will adhere to WAME's definition on editorial independence (CMA, 2016b). The *NEJM* does not have a JOC, but does have a policy on editorial independence (NEJM Journal Watch, 2013), and while the *BMJ* does not have a JOC, it claims to have other mechanisms in place to ensure editorial independence (Smith, 2004), though it does not expand upon what these are. None of the 'contentious case' journals in my sample have JOCs. This includes *JAACAP*, the journal that published the ghost-written controversial article Study 329 on Paxil (Keller et al., 2001), which misrepresented data (McHenry, 2005, Jureidini et al., 2008, McHenry and Jureidini, 2008) (see Section 2.4, Chapter Two). A medical publishing critic who I interviewed stated that they felt the failure of the current EIC of *JAACAP*, Andrés Martin, to retract the study was because *'he's having his strings pulled by other people, and he's not able to act with his own discretion here.'* The 'other people' referred to were the journal's owners – the American Association of Child and Adolescent Psychiatry – of which several of the authors of the article in question were past presidents. This provides an example of COIs that stretch beyond the traditional 'author' and 'reviewer' groups.

While the professional publishing associations do refer to the COIs that can arise between editors and owners, only the ICMJE and CSE discuss JOCs as a way of managing them. ICMJE advises on the establishment of independent editorial advisory boards 'to support editorial decisions and potentially controversial expressions of opinion' (ICMJE, 2013, p. 6). CSE recommends that journals and their owners should consider having JOCs, but does not give practical advice on how these could be set up and managed, stating only that:

‘An independent and objective journal oversight committee for performance review and evaluation for conflict resolution should be considered.’ (CSE Editorial Policy Committee, 2012, p. 42)

There was no discussion of JOCs on the websites of the majority of the journals in my sample. There was limited mention, in interviews, of editorial freedom, and only one interviewee – EIC3 – explicitly referred to JOCs, explaining that their journal has one and that they have found it to be effective in terms of protecting the editor from the demands of the journals’ owner, and vice versa. Thus, while JOCs should theoretically help to protect editorial decisions from receiving undue pressure from publishers and owners, my analysis of the interviews and the guidance and policies indicates that they do not appear to be a common feature of journals. Further, the fact that the CMA set up a JOC in 2003 (Hoey and Todkill, 2003), yet continued to apply pressure to its editors regarding publications, before firing them in 2006 (Willinsky et al., 2007), and then in 2016 disbanded it altogether alongside the letting go of its new EIC, John Fletcher (Kermode-Scott, 2016, Smith, 2016), indicates that even where there have been JOCs, they have not always been successful in protecting editors. Ultimately, if the JOCs inconvenience the journal owners, they can simply abolish them and get rid of the editors anyway.

While the uptake of JOCs is limited, the professional associations do refer to other ways in which editorial independence can be protected. For example, CSE’s White Paper says that journals:

‘should have a stated policy on editorial independence, and a disclaimer indicating that material published in the journal does not represent the opinion of the publisher, sponsoring society, or journal owner should be published regularly.’ (CSE Editorial Policy Committee, 2012, p. 42)

ICMJE, COPE, CSE and WAME all recommend having contracts between EICs and their publishers and/or owners, which make clear the terms of their relationship (COPE, 2011, CSE Editorial Policy Committee, 2012, ICMJE, 2014c, WAME Editorial Policy Committee, 2009, COPE, 2016b). WAME further says that these contracts should be ‘shared with readers by publication in the journal or on its website’ (WAME Editorial Policy Committee, 2009). However, none of my sample

journals make such contracts publicly available on their websites. As such, while CSE and WAME state that policies and contracts on editorial independence should be made public, this guidance does not appear to be widely followed. Only one interviewee (a publisher) made reference to contracts as a means for managing COIs: when I asked about editors' disclosure of COIs to their publishers, she said '*Editors have a contract agreement with us*' (Ann Lloyd, Elsevier). However, she did not expand on this, so the implications are unclear.

### **7.3 Further suggestions to improve the management of conflicts of interest and bias**

Chapter Six explored how voluntary disclosure is presented as the primary method for managing COIs in medical journal publishing. So far, this chapter has drawn on the data (publishing policies and guidance, and interviews, as well as the literature review) to provide an overview of mechanisms, beyond disclosure, that are already to varying extents in use, which have the potential to be used to assist in the management of COIs. However, as shown, these have only a limited effect in this regard. A medical publishing critic interviewed expressed concern that such processes are simply '*a public relations manoeuvre*' (Leemon McHenry, Medical Publishing Critic), aimed at improving the image of medical journal publishing and the affected industries, rather than effectively preventing bias from impacting on articles. Further, he worried that industrial sector companies, authors, journals and publishers could not be trusted to uphold and abide by the precautions put in place. Arguably, more fundamental changes are required. The following section now presents further suggestions made by interviewees of alternative ways that could be considered as a means of managing COIs in medical/health journal publishing.

The first to be discussed envisages building on the way in which disclosure is used to manage COIs. When asked how conflicts could be better handled, a central repository of disclosures was the most frequent suggestion made by interviewees (11 in total: five editors, one publisher, two medical writers, a

pharmaceutical company representative, a medical publishing critic and an author). The suggestions that follow this propose more fundamental alterations to the process of both medical research and publishing. Those interviewees (primarily medical publishing critics who provided a more critical voice than the majority of those embedded within the institutional environment) who raised these as possible ‘solutions’ to the problems of COI, criticised the industry’s focus on voluntary disclosure. They argued that, while it gives the impression that the industry is tackling the problem, it is in practice ineffective.

### ***7.3.1 Central repository for conflicts of interest and funding information***

As discussed in Chapter Six, the management of actors’ (including authors’, editors’, reviewers’ and medical writers’) disclosures can be a difficult task, which is reliant on honesty and self-regulation. When asked for suggestions as to how it could be improved, 11 interviewees (from across the range of actor groups) raised the idea of developing a central repository that hosts the COI information of researchers (ideally including authors, reviewers and editors). This would offer a way of storing and accessing actors’ COIs, which would improve transparency further. Jason Roberts (managing editor) also suggested that a central repository could be used to store information on clinical trials, rather than the onus falling on the journals to collect it. However, these interviewees acknowledged various possible difficulties with such a system, including the fact that such a database would still be based upon the principles of disclosure.

Four of my interviewees argued that a central repository would save both the journals and authors work. Journals are often limited in terms of resources, and this would save them time as they would no longer have to request completed disclosure forms and statements from each author: they could simply ask for authors’ database IDs. It would also benefit authors, who would not have to fill in different forms – in varying formats, with differing requirements – each time they submitted articles, as suggested by this author, who expressed irritation about having to constantly complete different forms:

*'there ought to be some kind of publicly available repository where you could stash most of the stuff, which could then be looked up by anybody.'* (A4)

While some interviewees complained that detailed disclosure forms are often impractical – for example, it can be hard for editors to get authors to submit them, and readers may not actually read them – a frequent criticism raised by interviewees of current disclosure policies was that they do not offer sufficient detail. Two interviewees suggested that a central repository would allow the disclosure of a greater level of detail regarding funding and other financial relationships, which could be pertinent, while summaries of COIs could be published on articles:

*'It would be nice to have this whole database format, so what company you have a tie with, what's the nature of the tie, and how much money do you get ... I'd like to see all that delineated ... I think the level of information I'm asking for would be too much to put in the article, but I would love to see some summary and then a link to the actual data.'* (MPC3)

*'These categories like, "have you accepted more than or less than \$5000?" So that the guy who got \$5000 as reimbursement is equivalent to somebody that's got \$2 million. There's not enough gradation there. The threshold is not the issue. It's what the actual dollar amount is.'* (A4)

Further a central repository would allow editors, reviewers and readers to access information on conflicts that, while not directly relevant, may still have had some indirect influence. Such a repository, therefore, would offer a more complete picture of actors' potential COIs.

Potential problems that may emerge when trying to establish such a repository were raised. One interviewee was concerned that such databases would not provide enough detail on conflicts relevant to specific articles:

*'A lot of the transparency databases ... they don't always match up exactly with the disclosures of the authors, because they're different time periods. So I do think for each article we need to have a specific disclosure.'* (MPC3)

Another interviewee countered this, arguing that people generally focus on one area of research. Additionally, they felt that such a database would offer information on wider relationships that may entail a potential conflict, which

actors may not consider immediately relevant to a current piece of work, and therefore may not have disclosed. Those viewing the database would thus develop a more complete picture of the relationships that could have influenced actors.

Two interviewees queried how such a database would be managed and enforced. One of these, a representative from the pharmaceutical industry, further questioned who would fund it:

*'What you probably need would be for some organisation to take this on and then go out and seek sponsorship ... I'm sure the [pharmaceutical] industry would contribute, but it shouldn't be entirely an industry, maybe it's the publishers, some from publishers, some from industry. Maybe some from government funds?' (PR1)*

One interviewee suggested that it would help if associations such as the ICMJE and COPE supported such an incentive, especially if they then encouraged journals to adopt a stance whereby they would only publish registered authors. However, as shown in Section 7.2.1.1, such endorsement has not been entirely successful with regards to CTR, and therefore could not be relied on to necessarily work with this. Another interviewee proposed that professional bodies or universities insist that their members and employees sign up; however, given that many researchers work outwith such organisations, there would also need to be buy-in, for example, from manufacturing sector companies. Further, as with the current process of disclosure, a central repository of potential COIs would be reliant on the honest disclosure of individuals.

There have been moves towards developing such repositories. The Physicians Sunshine Act, introduced in the US in 2010, requires the manufacturers of drugs, medical devices and biologicals that take part in US federal health care programmes to report consulting fees, research grants, travel reimbursements, and other gifts that are given to physicians and teaching hospitals (cms.gov, 2014, American Medical Association, n.d.). These are stored on the cms.gov website (Centers for Medicare & Medicaid Services, n.d.).

However, as one interviewee pointed out, this only captures payments made by the industries listed above; researchers may receive funding from other industries, such as tobacco, drink or food, which also ought to be disclosed with articles:

*'A lot of research is done by people who are not physicians, they might be epidemiologists, statisticians, or whatever. They might have taken money not just from pharma, but from the food industry.'* (SE2)

Additionally, this is only applicable in the US, and only covers physicians; other medical researchers would not be included on the database.

ORCID, which launched its registry services in October 2012 and is funded by a variety of publishing organisations, is a database that links research activities and outputs to researchers. Researchers who sign up to it can input details of their research activities (such as manuscript submissions, grant applications and patent applications), which are linked to their unique personal identifier numbers. ORCID was the subject of seminars at a Council of Science Editors conference I attended,<sup>24</sup> and was discussed by five interviewees (a publisher, a medical writer and three managing editors). While it has not been designed specifically to manage researchers' COIs, these interviewees suggested that it does have the potential to be further developed to assist with this:

*'I would love there to be a central repository that every journal could tap into. Maybe it'll happen with ORCID and everyone submits their ID. I won't even ask them to give me a conflict in future, I'll just literally have their ORCID number and I'll just key in the number. Boom, it'll pull it out.'* (Jason Roberts, Managing Editor)

They suggested that ORCID could act as the central repository and contain relevant financial information which could then be accessed by other actors. Another interviewee (an executive editor) referred to other existing databases such as PubMed, Scopus and Web of Science, saying that they currently have fields for funding information and suggesting their potential to fulfil such a role.

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<sup>24</sup> Council of Science Editors, Montreal, Canada, 3<sup>rd</sup> – 6<sup>th</sup> May 2013.



However, these interviewees perceived this as a hypothetical solution, and one that has not yet been expanded to capture such data.

### **7.3.2 Open data**

There has been a debate within medical journal publishing about ‘open data’ – that is, the making of raw data public (e.g. Boulton et al., 2011, Walport and Brest, 2011, Godlee, 2011a, Jefferson et al., 2011, Ebrahim et al., 2014, Henry and Fitzpatrick, 2015). Eleven interviewees from across the actor groups argued that raw data should be made more accessible. David Healy, a medical publishing critic, argued that this was more important than focusing on disclosure policies, which, he felt, do not address the real issue: that is, the pharmaceutical industry’s suppression of unfavourable data. He suggested that journals should insist on being provided with the data:

*‘The journals potentially have great power here, they could have insisted ages ago to the pharmaceutical companies that, if they wanted their trials published in a journal, that they hand over the data. But they haven’t done so. So the journals have shirked’* (David Healy, Medical Publishing Critic).

Making raw data publicly available would arguably improve transparency and accountability. As it stands, some journals do require that researchers supply them with the data for articles they have submitted. Giving the journals access to the data should, at the very least, force researchers to be more careful with how they portray their data, because editors and reviewers would be able to assess the results and analysis against the full dataset, providing, of course, that all the data have been provided:

*‘if you’re going to have to put all your data out in public, then you’re far more likely to have done all the quality control checks and the data’s accurate’* (Chris Proctor, BAT).

Currently, of my sample journals, only *JAMA*, the *BMJ*, *The Lancet*, *PLoS Medicine* and *JNCI* state that the raw data must be made available to the journal upon request. One interviewee (a medical writer) suggested that ‘most journals don’t have the resources to actually do that’ (Tom Lang) – that is, have statistical reviewers available who can actually make sense of the data (as discussed in

Section 7.2.2.2, many reviewers may not actually have the statistical analysis abilities to be able to interpret it sufficiently). Further, Jose Merino (Senior Editor, the *BMJ*) argued that such requests are ‘not enforceable’ unless all journals make them, as authors and companies could simply publish elsewhere. In order to encourage journals to require copies of the raw data, one medical writer (MW1) suggested that, as with CTR, organisations such as the ICMJE should endorse it and insist that their member journals do so. However, as discussed in Section 7.2.1, the success of this in other areas like CTR has been limited. It is interesting, however, that the comment above was made by a representative from the tobacco industry: he explained that his company (British American Tobacco) was looking for ways to make their clinical study data public (he did not know whether this reflected the tobacco industry more widely).

Five medical publishing critics who were interviewed argued that data from trials should be made publicly available, rather than only to the journals, so that others are able to reanalyse it and produce additional (and potentially alternative) interpretations of it (also, as discussed in Section 7.2.2.2, it would help peer reviewers when reviewing papers, providing they have the appropriate statistical analysis skills). One such interviewee (MPC3) explained that replication is the cornerstone of science; David Healy (a medical publishing critic) concurred, stating that to refuse to allow outside analysis is ‘*plain not scientific*’. Further, it would provide the opportunity, in cases where a study has been controversial, for it to be re-examined: making the data publicly available ‘*does allow that opportunity, if there is a lot of criticism of a study, then go back and see if they’ll get a different answer.*’ (MPC3) This was done with the data from SmithKline Beecham’s Study 369 on paroxetine (see Section 2.4 of Chapter Two): the data for this trial were reanalysed and published in the *BMJ* in 2015 (Le Noury et al., 2015). Being aware that their study might be replicated may help to reduce the likelihood of researchers consciously allowing their bias to affect their writing.

Joel Lexchin, a medical publishing critic, suggested a more fundamental change in the model of research and publishing, arguing that, rather than conducting the analysis and producing articles themselves, companies should put the raw data from trials on their websites, enabling others who are external to the company to examine and comment on it, with the journals providing the space where such analyses could be published. However, he felt that it is unlikely that either pharmaceutical companies or journals would support such a measure, arguing that the former would be unlikely to allow their data to be analysed by independent researchers (or potentially competitors), and that it would disrupt the journals' revenue streams (for example, they would no longer receive money from the pharmaceutical industry for reprints of articles that they have sponsored).

### **7.3.3 Alternative funding models**

When considering alternative ways to manage COIs, the medical publishing critics I interviewed moved beyond disclosure and made suggestions involving more deep-seated changes in the processes of both medical/health research and publishing. They argued that simply declaring interests is not sufficient for managing COIs, and felt that, rather than improving disclosure policies, the current system of funding and publishing needs to fundamentally alter, in order to prevent conflicts from occurring in the first place. For example, one interviewee stated unequivocally that:

*'It's abstinence that's required. I'm not a great believer that there's a form of safe intercourse to have with the pharmaceutical industry.'* (Jon Juredini, Medical Publishing Critic)

However, other interviewees from other areas of medical journal publishing expressed concern that without pharmaceutical industry funding, much important research would not be done. Acknowledging this (and rather than advocating an outright ban on the publication of such research), Juredini suggested that industry funding should be either routed through public institutions or through independent funding bodies. These could then hire or administer the funds to researchers to conduct studies on the products, rather

than sponsoring individual researchers (or conducting the research themselves). He argued that this could effectively place a 'firewall' between the researcher and the sponsor. However, previous experience in connection with the tobacco industry has shown that even measures such as this are not always successful, as will be explored in more detail in Chapter Eight, Section 8.4.4.

## **7.4 Concluding discussion**

The previous results chapters looked at the how thinking surrounding the topic of COIs in medical journal publishing, by those working within the field, is somewhat static. The interview data showed that actors, embedded as they are within the institutional environment of medical journal publishing (they are themselves an integral part of it), tend to focus on the accepted understandings of what comprises COIs and how they should be managed. However, as this chapter has shown, analysis of the data did identify several existing mechanisms which, although not their primary or only purpose, can assist with managing conflicts. Interviews also elicited some suggestions of additional ways in which COIs might be regulated.

A number of journals refuse to publish particular types of articles from authors with conflicts. The argument for this seems to be that bias is more likely to be hidden in articles such as commentaries or editorials. However, such articles are intended as opinion pieces, and therefore it is implicit that they will be slanted one way or another; further, as one interviewee pointed out, part of the role of journals is to act as a forum for debate. Preventing such articles would stifle it. It may also lead people to hide conflicts. If disclosure is considered by the industry to be an effective mechanism, it is not clear why it is not then sufficient for such articles. Similarly, one could argue that all research should be published, regardless of the provenance of its funding, providing disclosures are made. However, as the previous chapter demonstrated, disclosure is not always a fool proof process.

It was suggested that peer review plays a role in managing COIs. However, some interviewees queried the effectiveness of this process in general, and consequently whether it can be considered an effective way of picking up on bias in articles and undisclosed conflicts. Further, reviewers themselves, as an actor group, can be conflicted, and their own biases may affect their treatment of articles. For reviewers to effectively assist with the management of COIs, and resulting bias in the ways suggested by interviewees, they should be explicitly advised by the journals that this is part of their remit, and given help specifically on the ways in which they can do so, and also disclose their own potential bias.

Post-publication peer review was raised by a small number of interviewees as being an additional way for capturing conflicts. However, this can certainly not be relied on: ideally conflicts should be identified and mitigated before the research is published; afterwards is too late. In addition, in practice it would seem that realistically, few readers are likely to contact journals to alert them to undisclosed conflicts. COPE offers flowcharts of how editors should respond to claims of undisclosed conflicts by reviewers or readers; however, if authors deny such accusations, COPE's advice appears to be to simply take their word for it. It does not advise on any further investigations that should be undertaken. None of the journals in my sample currently offer information to readers on what to do if they know or suspect there to be undisclosed conflicts. If readers are to play a role in managing authors' COIs, after articles have been published, then journals should actively call on readers (on their websites, or articles themselves) to report any known, undeclared conflicts, instigate an easily used reporting mechanism, and provide information on what the journal's procedure is for investigating them.

Many of the additional mechanisms identified in the data specifically relate to authors, with less focus on other actor groups. The only additional mechanisms designed to manage conflicts between other actors (in this case, editors and journal owners), which was discussed by a minority of interviewees and referred to in some of the professional associations' policies/guidance, were

JOCs and contracts between editors and journal owners. If journals have provisions in place to protect editorial freedom, editors may be more willing to question decisions they are uncomfortable with. However, there is limited promotion by the professional publishing associations of initiatives such as JOCs. Further, as the recent firing by the CMA of its journal's editor in chief, John Fletcher, and the dismantling of its JOC (having been one of only two journals in my sample that had one), shows, they are perhaps in reality not all that effective a safeguard to protect editors against the COIs of their journal owners. Further, despite the recommendation of ICMJE, COPE, CSE and WAME that contracts exist between editors and their journals' owners, with the latter two associations advising that these contracts be made public, none of the journals in my sample appear to publish such documents.

While some interviewees cited CTR as being a mechanism that had alleviated problems of publication bias and inaccurate reporting of trials, the fact that not all journals (including four in my sample) or publishers refer to it in their guidance/policies and submission systems suggests that it is not currently ubiquitous enough to act as a means of managing COIs at an industry level. It is unfortunate that many journals do not check whether clinical trials are registered or not, as it is a potentially useful tool in the reduction of publication bias. Similarly, not many journals appear to employ other processes that have the potential to help reduce conflicts and resulting bias from impacting on the published literature, such as CTP. The reporting guidelines also appear to be under-utilised: this may be because, as one interviewee argued, there are too many of them, and as such, publishers and editors may be confused as to which to endorse and therefore not recommend any. Clearer guidance on this could be offered by the professional associations.

The chapter continued by presenting interviewees' suggestions of ways in which COIs and associated bias could be more effectively managed than current approaches. The most frequently proposed was a central repository where COI disclosures could be stored. This is perhaps unsurprising, given the dominant

role voluntary disclosure currently plays in the process of managing COIs, as discussed in Chapter Six, and demonstrates how ingrained it is in the thinking of actors within medical journal publishing. Section 7.3.1 highlighted some of the potential benefits of such a database. For example, it would not only be applicable to authors, but rather all actors could be registered. Thus, for example, editors could easily look up authors', reviewers' and contributors' COIs, and readers could check to see the potential COIs of authors and editors. While some readers may not be willing to go and check such a database themselves, it could possibly generate a statement for editors to include with articles. It could also become, as suggested by Jason Roberts (managing editor) a place where information on clinical trials could be stored and accessed, thereby taking the onus of responsibility for collecting this off journal editors. However, such a database would still rely on the honesty of individuals, and their ability to keep it up-to-date. It would therefore perhaps be more effective if an independent organisation maintained and enforced it; this would need to be funded in such a way that did not in itself entail conflicts.

Other suggestions were made by a smaller number of interviewees with regards to altering the fundamental models of both medical research and publishing: alternative funding models and open data. However, these interviewees acknowledged that such changes are unlikely to occur in reality. For example, it is unlikely that pharmaceutical companies would agree to pay for research over which they had no control. With regards to the debate over making raw data publicly available, this would allow controversial studies to be reanalysed. However, many researchers may be unwilling to be involved in such work: they may find it hard to get funding for it, and journals that are willing to publish them. These interviewees argued that there are too many interests vested in the current system of medical research and publishing for such larger changes to occur.

The previous two chapters demonstrated how ideas surrounding the topic of COIs within medical journal publishing are relatively constant and unvarying

– in terms of what constitutes a conflict, who can be conflicted, and how such conflicts can be managed (principally through disclosure) – with those working within the institutional environment finding it difficult to consider alternatives. This chapter, however, identified several existing additional processes, examining how effective they are. Yet while in theory these may be useful in assisting in the management of COIs, in practice they are not effectively employed, with limited uptake and enforcement. Some medical publishing critics suggested that this was because attempts at developing such processes are merely for show, rather than serious efforts at tackling the problem. However, much of the interview data demonstrated an engagement with the questions, but suggested that there are practical difficulties in addressing them, particularly for smaller, less well-resourced journals. A greater exploration of these is needed if they are to be useful.





# CHAPTER EIGHT: DISCUSSION

## Examining the institutionalisation of conflicts of interest and possibilities for change

### 8.1 Introduction

The aim of this qualitative research thesis was to explore both the conceptualisation of COIs in medical journal publishing and the impact this has on their management, and to consider how this might be improved. The primary research question was: *To what extent does the institutional environment of medical journal publishing inform actors' conceptualisation and management of conflicts of interest and their consideration of alternative approaches?* Through an analysis of a sample of publishing guidance, policy documents and 48 interviews, the results chapters (Chapters Five, Six and Seven) have shown that within the institutional environment of medical journal publishing there exists a relatively narrow understanding of what COIs are, which actors have conflicts that require regulation, and how they should be handled. However, as Chapter Two demonstrated, other actor groups can have conflicts that can affect the journal literature; they can be caused by a range of interests beyond financial; and disclosure is not on its own an entirely effective form of managing them. It is therefore argued here that this limited conceptualisation of conflicts limits their successful regulation.

After providing a summary, in Section 8.2, of the main findings outlined in the previous three chapters, this chapter explores the results in greater depth, pulling them together, in order to answer the question posed above. Section 8.3 explores several theories of institutionalism (e.g. Mahoney and Thelen, 2010, Scott, 2014, Peters, 2012, Tolbert and Zucker, 1996, Furusten, 2013), relating

them to the topic of this thesis and the research question to explain the existing relatively narrow conceptualisation of COIs. It explores how particular ideas regarding COIs (what they are, who can have potential relevant conflicts, and how they should be managed) can be understood as having become institutionalised within medical journal publishing. Section 8.4 draws further upon theories of institutionalism, including those that explore the dynamics of change (Oliver, 1992, Scott, 2014, Tolbert and Zucker, 1996, Dacin et al., 2002, Schmidt, 2010c, 2010a). In doing so, it allows us to consider the possibility of ideas and practices regarding COIs altering, thus enabling more effective management of them. This section then examines how COIs and their management could be reimaged, reflecting on several of the suggestions that emerged through the data of adapted or new ideas, and relating them to the institutionalist theories discussed. Section 8.5 identifies directions for future research, building on the findings in this thesis. The implications of this research, both for medical journal publishing and, more broadly, for public health policy, are considered in Section 8.6. Finally, Section 8.7 discusses the strengths and limitations of this research.

## **8.2 Summary of the main findings**

The results chapters (Chapters Five, Six and Seven) offer a thematic analysis of the data, which allows us to explore the ways in which COIs are conceptualised within the institutional environment of medical journal publishing. Chapter Five explored the ways in which COIs are conceptualised in medical journal publishing, in terms of both understandings of who it is that can be conflicted and of what types of interests can pose conflicts. Analysis of the sample policies/guidance and interviews, in Section 5.2, showed that a heavy focus is placed on the conflicts of named authors, while other actors such as reviewers and editors are discussed less, and journal owners and contributors (such as medical writers and statisticians) are given very limited attention. The interviews further demonstrate that the range of actors beyond authors who are perceived as possibly having conflicts that require management is rather narrow. The result of this restricted perception is that any conflicts that these broader

groups of actors involved in medical journal publishing have may remain unmanaged. Yet, what limited discussion there is of these actors, both in the primary data (see Chapter Five, Section 5.4) and the literature (see Chapter Two, Section 2.3.1), shows that they can in fact potentially be conflicted in a variety of ways, and that these conflicts can affect publications in medical journals. Chapter Five also showed that in medical journal publishing, there is a concentration on financial COIs – particularly funding and personal financial interests – while non-financial ones (such as academic commitments, personal relationships, political or religious beliefs, institutional affiliations and career advancement) are marginalised, despite the fact that it has been argued that they can also pose problematic conflicts that can have an impact on studies and the resulting literature (PLoS Medicine Editors, 2008, Marcovitch et al., 2010, Saver, 2012). The findings of this chapter therefore indicate that publishing guidance and policies should be broadened so that they capture a wider range of actor groups and interests that could have an impact on medical/health journals, thus ensuring that they are managed.

The thesis continued, in Chapter Six, by examining the primary way in which COIs are managed in medical journal publishing. It demonstrated that the majority of guidance and policies from across the range of organisations emphasises self-disclosure as the principal mechanism for managing COIs (and often offers no other specific suggestions). The reliance on disclosure was also echoed in interviews when discussing how conflicting interests are regulated. Reflecting the findings in Chapter Five, Chapter Six shows that the practice focuses on the actor group most widely identified as being significant – authors – with the requirements for other groups of actors being far more variable and vague; where advice on the management of their COIs is provided, it is again based on disclosure. The lack of attention given to these actors was reflected in interviews, with only limited discussion on editors, reviewers, journal owners and medical writers. Thus, this chapter shows that the main mechanism for managing COIs in medical publishing is self-disclosure and that this is largely directed towards authors, with other relevant actor groups being largely ignored

(as might be expected, given the extent to which conceptualisations of COIs also focused on authors, as discussed in Chapter Five).

While Chapter Six showed there to be a heavy focus on disclosure, Chapter Seven demonstrated that there are a number of existing additional mechanisms that have the potential to help manage COIs in both the process of medical research and the resulting literature. For the former, these were: Clinical Trial Registration, Clinical Trial Protocols and Reporting Guidance; the latter involved: non-publication policies, peer review and Journal Oversight Committees. These primarily relate to authors' conflicts (with the exception of the latter, discussed by only one interviewee). While these do appear to be potentially useful tools, the analysis developed in Chapter Seven indicated that so far, the uptake of them for this purpose has been, to varying degrees, limited, and thus they do not currently in practice play a substantive role in managing COIs in medical journal publishing. When asked about other mechanisms, beyond self-disclosure, that could assist in improving the management of COIs, interviewees frequently suggested the development of a central database where disclosures could be stored. Only a limited number of interviewees who have been involved in work critiquing the medical journal publishing industry (referred to in this thesis as 'medical journal critics') articulated more innovative systems. Thus, this chapter identifies and brings together several existing additional mechanisms that could be more usefully employed in the task of managing COIs, as well as exploring potential new ideas.

### **8.3 The institutionalisation of conflicts of interest: Establishing and maintaining ideas**

There exist various definitions of institutions, which have emerged from disciplines such as organisational and management studies and political science. These definitions vary from formal structures to more nebulous concepts (see Mahoney and Thelen, 2010, Scott, 2014, Peters, 2012, Hodgson, 2006, Jepperson, 1991, Tolbert and Zucker, 1996); however, it is generally agreed that institutions

are comparatively stable and on-going facets (rules, norms, understandings and procedures) of political and social life, that structure and/or constrain behaviour, and that can be difficult to change. This thesis considers medical/health journals as a form of institution, and examines the conceptualisation of COIs within them, as well as the wider 'institutional environment' (Furusten, 2013) of medical/health journal publishing within which these journals operate (as mapped out in Chapter Three). This section examines how ideas regarding COIs and their management within the medical journal publishing industry are restricted and have become institutionalised, impeding the ability to more effectively control their effect on the journal literature.

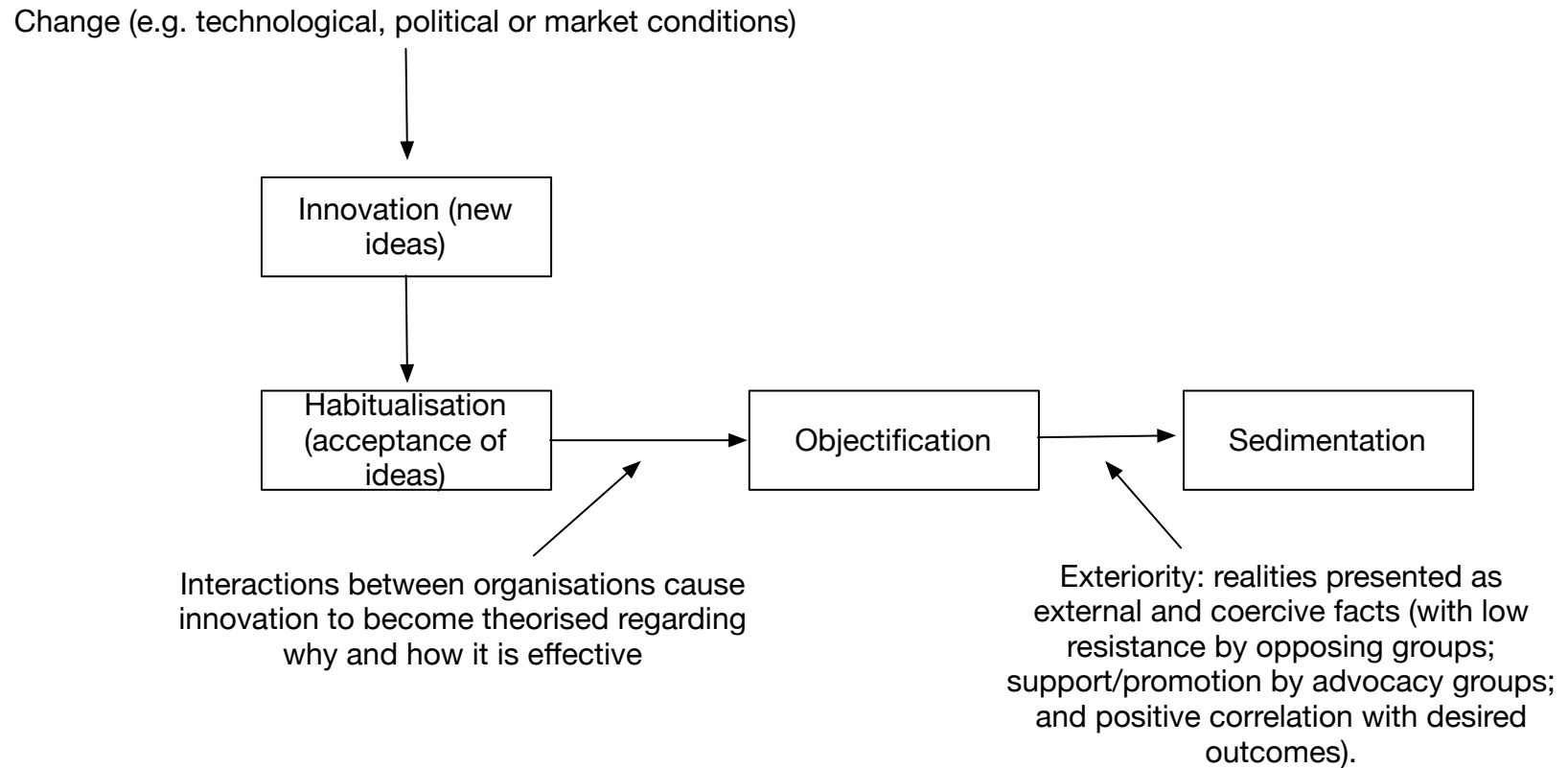
Persistence and stability are key characteristics of institutions (Mahoney and Thelen, 2010), and this thesis looks at how particular ideas surrounding COIs have taken hold and are maintained within the institutional environment of medical journal publishing. As demonstrated in Chapters Five and Six, certain actor groups' COIs, and particular types of interest, are focused on, and the management of these through the process of disclosure is emphasised. Other actor groups, and other forms of interest, are marginalised and even excluded from the debate. Drawing on theories of institutionalism (e.g. Mahoney and Thelen, 2010, Scott, 2014, Peters, 2012, Tolbert and Zucker, 1996, Furusten, 2013), this research explores how certain ideas regarding COIs in medical journal publishing appear to have become widely established as norms, and thus dominate the discussion, squeezing the imaginative potential for more radical alternatives. Through doing so, we are better able to understand the barriers to the emergence of new ideas.

Institutionalisation is a process that occurs over time, and results in a set of stable social arrangements (Jepperson, 1991). Ideas, which shape behaviour, gradually become established, involve shared definitions and meanings and are rarely questioned (Furusten, 2013, Tolbert and Zucker, 1996). An example in relation to this research are those ideas surrounding the topic of COIs and their management in medical/health journal publishing. These ideas become so

habitualised that they are evoked in response to certain stimuli with little decision-making effort by actors (Tolbert and Zucker, 1996). For example, most of my sample guidance emphasises disclosure in their sections on COI management, and when interviewees were questioned about how COIs should be managed, the majority referred to disclosure and did not appear to consider alternatives (see Chapter Six).

There are debates as to exactly what causes the institutionalisation and domination of particular ideas (this may, of course, vary by context and example), but it is commonly observed that some ideas become so established that they are taken for granted (Furusten, 2013). However, Tolbert and Zucker (1996) developed a framework of ‘increasing objectification’ to explain the mechanisms that lead to institutionalisation. This builds on Berger and Luckmann’s (1966) discussion of ‘objectification’, whereby ideas or behaviours are presented to actors (who had no part in constructing them) as facts, and thus become the norm and are embedded in a particular social system. Tolbert and Zucker (1996) argue that institutionalisation involves three sequential processes: ‘habitualisation’, ‘objectification’ and ‘sedimentation’ (see Figure 8.1). ‘Habitualisation’ is the development of particular patterned, problem-solving behaviours which become shared definitions or meanings, and are evoked with minimal decision-making effort by actors in response to certain stimuli. These ideas become independent of the specific individuals who utilise them, and this is the process of ‘objectification’. A later stage is ‘sedimentation’, which is the process through which these objectified ideas become embedded in the material world, with actions and ideas spreading through the relevant population, acquiring the quality of exteriority and becoming understood to be a reality: an external and coercive fact (Berger and Luckmann, 1966).

Figure 8.1: Component processes of institutionalisation



(Adapted from Tolbert and Zucker, 1996, p. 182)



Tolbert and Zucker's framework, applied to this research, clarifies how particular ideas surrounding COIs have developed and become habituated over time, with more actors taking them up (see Figure 8.2). The process of habitualisation can be understood to occur at the pre-institutionalisation stage, when organisations develop structural arrangements in response to a specific problem. In the context of this thesis, this can be understood as having occurred in the 1980s and 1990s. This was when the topic of COIs began to be recognised as an issue in medical journal publishing: in response, the *NEJM* developed a COI policy in 1984, (Kassirer and Angell, 1993, Relman, 1984), with other journals gradually following suit. In doing so, they formed ideas, contained within these policies, regarding what COIs are, who might have COIs that require management, and how they should be dealt with. Tolbert and Zucker argue that adoption of similar solutions by a comparatively limited number of other organisations, convinced by the balance of costs and benefits, is likely to follow if they are technically and economically viable (1996), which the development of COI and disclosure policies and processes, as a low-cost but seemingly effective solution, appears to have been.

In 1997, the ICMJE revised its *Uniform Requirements for Manuscripts Submitted to Biomedical Journals Studies*, stating that authors should acknowledge financial and material support, and disclose relationships that may pose a COI (ICMJE, 1997). This perhaps signalled the beginning of the objectification stage of these ideas surrounding COIs, with a consensus being agreed regarding these structures and them thus becoming diffused through the medical journal publishing institutional environment. As the studies on journals' COI and disclosure policies that were discussed in Chapter Two, Section 2.5.2 show, from 1997 onwards, the number of journals that had such policies increased. The ICMJE appears to be a particularly influential organisation, playing a key role in determining what it is that gets classified as an ethical issue and how it is managed, despite the fact that it is, as argued by a number of interviewees, a closed group, comprised of the top medical journals, which are not representative of, and do not necessarily have an awareness of, the realities

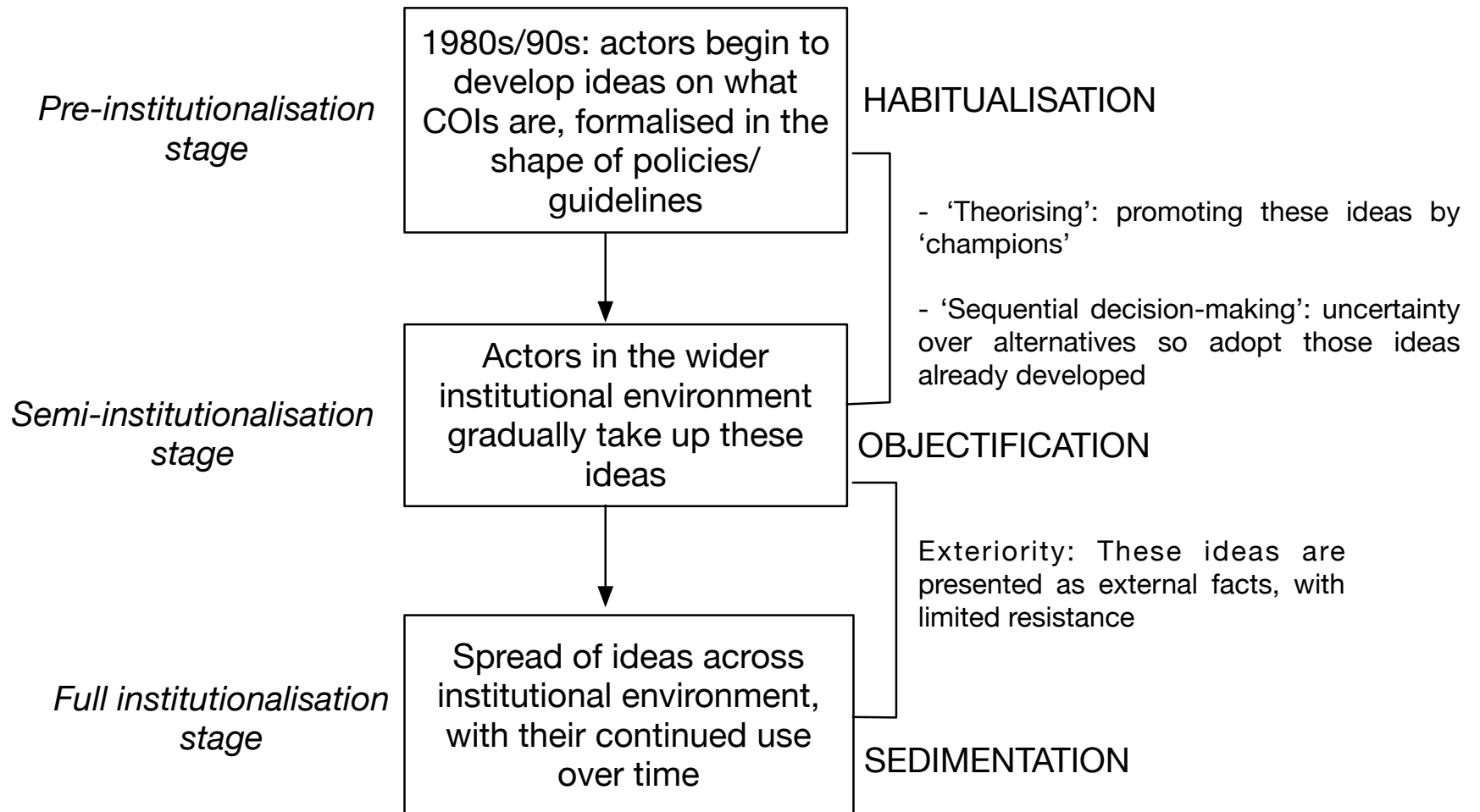
facing smaller, less well-resourced journals. Despite the fact that the resources it has produced, such as its authorship criteria and COI disclosure form, were criticised by some interviewees, analysis of my sample journals demonstrates an on-going commitment to them. My data indicate that this is because the ICMJE member journals are considered to be leaders in the field, rather than through any clear appraisal of their policies.

Tolbert and Zucker (1996) discuss several ways in which objectification and diffusion of a structure can occur; one of particular relevance to this research is the sequential decision-making one. Faced by uncertainty over the outcomes of alternative choices, journals, publishers and other professional associations will follow the same course of action as others have done, adopting similar structures/ideas (in this case, COI policies). As they became increasingly widespread, it is harder for different choices to be considered: this is the stage of semi-institutionalisation. 'Champions' of COI disclosure policies – those individuals 'with a material stake in the promotion of the structure' (Tolbert and Zucker, 1996, p. 183) – will also push objectification through the process of engaging in theorisation, that is, creating a definition of the problem and justifying their solution: this leads to their ideas being developed and becoming objectified. In the case of this research, these 'champions' can be understood to be the early adopters of COI policies who recognised that there was a problem which threatened the integrity of their work (the journals) and thus developed a solution which seemed to be easily implemented and of low-cost. Through their theorisation – formalising their ideas in the shape of guidance/policies – and at least some evidence of their new structure's success (such as authors meeting their disclosure requirements), these new structures/ideas are provided with cognitive and normative legitimacy. These ideas are presented to other actors within medical journal publishing as objective facts – for example, that disclosure is the method through which COIs should be managed – thus limiting the ability for new ideas to be considered. As the theorisation develops and becomes more explicit, variations between the organisations in the structures they adopt will decline and become more homogeneous, with them all adopting

similar policies and processes (Tolbert and Zucker, 1996).

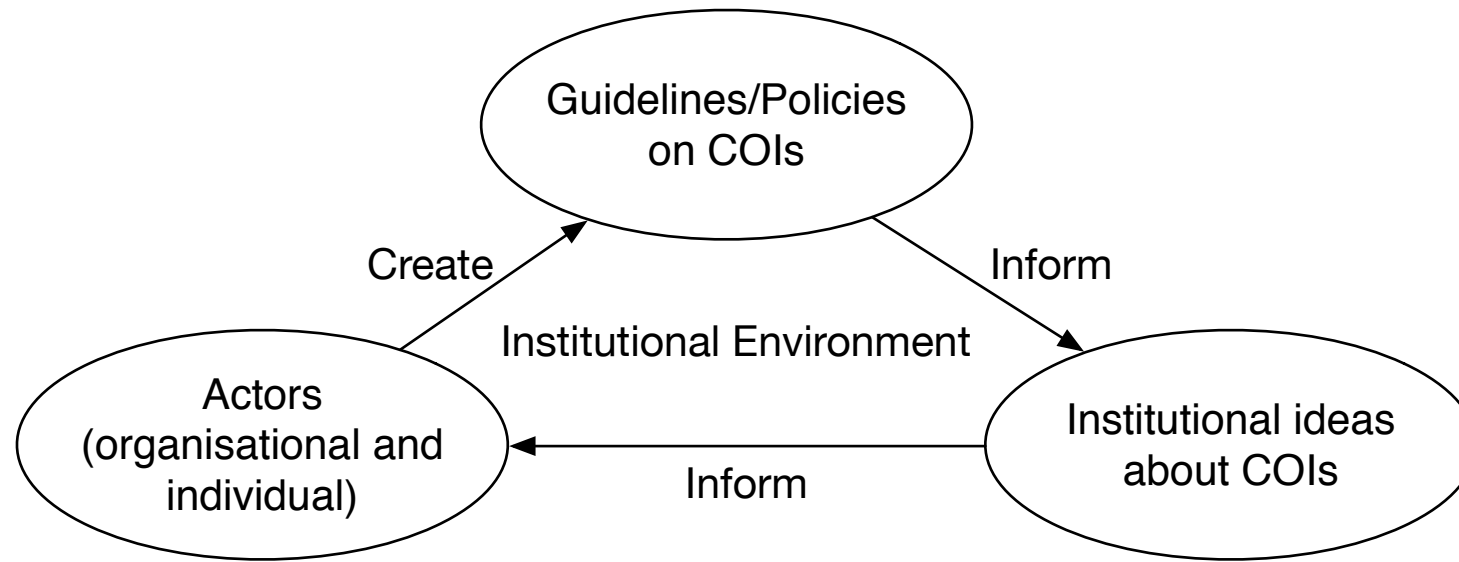
For full institutionalisation to occur, sedimentation is required. This is the spread of structures across almost the whole group of actors considered to be potential adopters, and their continuing over a long period of time. In the absence of alternatives or resistance by actors who oppose it, and the continued promotion by the 'champions', the structure is likely to perpetuate and become institutionalised. Furusten (2013) argues that, as new actors enter the institutional environment, they will for the most part automatically subscribe to these pre-existing ideas as they have become the norm. My data analysis demonstrates that the way COIs are conceptualised, and their management through disclosure, has become standardised through the institutional environment of medical journal publishing. Tolbert and Zucker (1996) suggest that a positive correlation with desired outcomes is also required; while it has been demonstrated that disclosure is not entirely effective in managing COIs in medical journal publishing, it could be argued that it offers those promoting it the appearance of tackling the issue as best they can, at limited cost to themselves, and therefore it can be considered efficacious to them.

Figure 8.2: Tolbert and Zucker's processes of institutionalisation (1996) applied to ideas regarding COIs in medical journal publishing



The data presented in Chapters Five, Six and Seven show that the actors working within the institutional environment of medical journal publishing appear to have difficulty in conceiving alternative ideas to those that have become institutionalised. The sample documents and interview data all demonstrate to a large degree this institutionalisation and limitation of ideas surrounding COIs, with a focus on particular actors, types of interest, and management through disclosure. Once the ideas have become objectified, and the sedimentation process is underway, it is difficult for new ideas to enter the institutional environment. The existing policy/guideline documents inform the sentient agents' understandings of COIs; they in turn are responsible for developing new versions of these documents. Thus, once objectification and the semi-institutionalisation stage has been reached, with these ideas presented as external facts, this circular process (Figure 8.3), means that it is difficult for new ideas to enter the institutional environment and for change to occur. This is particularly the case because a number of the same individuals (particularly from high impact factor (IF) journals) appear in key positions in the majority of the professional associations, which inform the understandings regarding COIs of journals and publishers. This can be seen as facilitating sedimentation and full institutionalisation.

Figure 8.3: The circular flow of ideas on COI in the medical journal publishing institutional environment



(Original diagram.)

How particular ideas surrounding COIs become established over others in the first place, and the interests of those involved in the development and maintenance of these ideas, is also important to consider. As demonstrated in the results chapters, the journals and their owners are themselves faced with COIs, for example through being often financially dependent on income from manufacturing sector companies (such as from the pharmaceutical and tobacco industries). They may therefore have a vested interest in developing particular understandings of COIs. The professional associations, as discussed above, are comprised of individuals from the journals and publishers (as well as pharmaceutical companies and medical writing companies). This means that not only may they fail to manage their own conflicts with regards to medical journals sufficiently, but that their very conceptualisation of what COIs are, and how they should be managed, may be influenced by those interests. However, as shown in Chapter Two, Section 2.2, financial interests are not the only type of interests that can cause conflicts, and are also not the only ones that motivate actors (Woll, 2008, Schmidt, 2008b, Gieyrn, 1983). Actors are socially embedded and may have a plurality of interests besides economic ones. For example, while editors will want their journal to be profitable, it is also reasonable to assume that they will want to publish research that has been conducted ethically and furthers knowledge in their field. It is thus probable that while some editors may be influenced by financial interests when developing policies, they also do genuinely wish to limit the problems caused by COIs and improve the integrity of the medical journal literature. Therefore, while their own potential COIs should be taken into account when considering the ideas that they have developed surrounding COIs, these actors could play a valuable role in developing improved ways of understanding COIs and as such should be involved in the process.

#### **8.4 The possibility of changing ideas**

The previous section looked at various theories of institutionalism to explore how ideas within organisations become institutionalised, accepted as the norm

and established reality. This work was applied here to frame how certain understandings of COIs have taken hold within the institutional environment of medical journal publishing. My research also explored the potential for shifts in ideas and practices, and whether it might be possible for alternative approaches for managing COIs to be developed. The following section begins by looking at theories of change (Oliver, 1992, Scott, 2014, Tolbert and Zucker, 1996, Dacin et al., 2002, Schmidt, 2008b, 2010b, 2010c, 2010a), namely the ways in which fresh ideas can potentially enter an institutional environment, causing existing established ones to break down or become amalgamated with emerging ones. Alternative suggestions identified in the data (such as journals that offer wider definitions of COIs, or interviewees who provided alternative suggestions for their management) are explored in order to examine the possibility of changing established ideas surrounding COIs. Sections 8.4.1 and 8.4.2 discuss theories based on more gradual, incremental change (Mahoney and Thelen, 2010), adjusting concepts already established, such as the understanding of COIs and their management. These can be achieved, for example, through the interaction of actors using their 'foreground discursive abilities' (their ability to think critically outside their institutions) (Schmidt, 2008b, 2010c, 2008a, 2010a) and the process of bricolage (rearranging existing elements of ideas within the institution to develop new ones) (Campbell, 2005, Schmidt, 2010a, Carstensen, 2011). Sections 8.4.3 and 8.4.4 look at ideas that are more paradigmatic, but may also come about through the critical thinking of actors using their 'foreground discursive abilities'.

Institutional theories have in general developed to try to understand empirically observed stability and inertia, and are therefore less useful in explaining change. Some institutional theorists assume that once ideas have become institutionalised, this stability or inertia (resulting, for example, from habitualised behaviour, as discussed in Section 8.3) means that change is unlikely to occur (Hannan and Freeman, 1984, Jepperson, 1991, Powell and DiMaggio, 1991). For example, Powell and DiMaggio wrote that, 'Things that are institutionalized tend to be relatively inert, that is, they resist efforts at change'



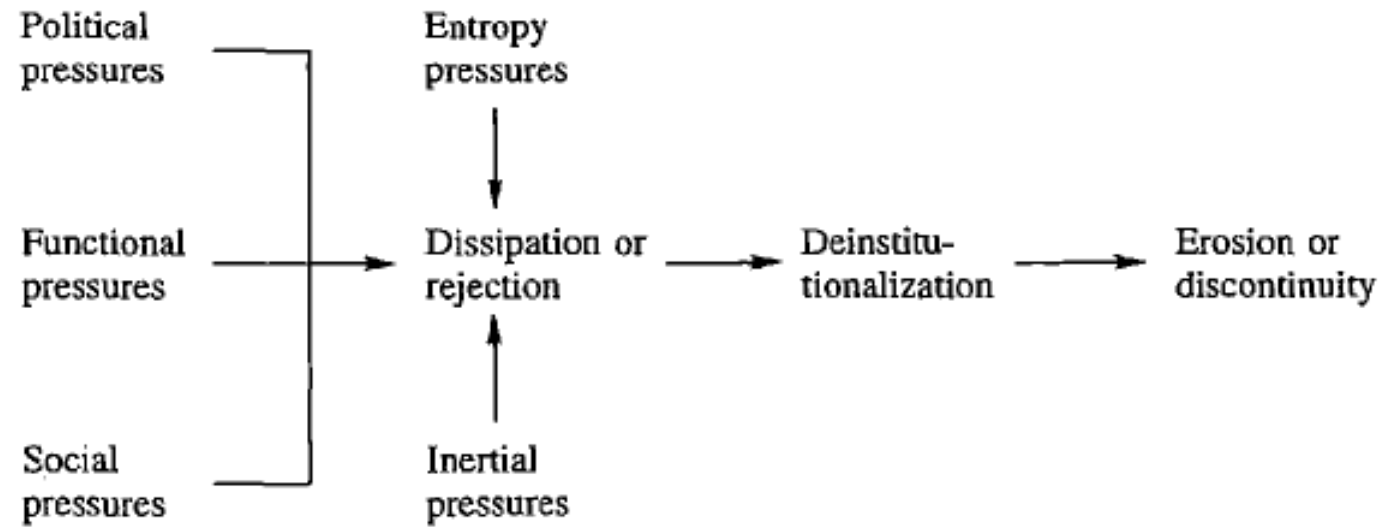
(1991, p. 197). As this chapter has shown, through the use of Tolbert and Zucker's (1996) framework, we are able to understand how certain ideas regarding COIs within medical journal publishing – as demonstrated in the results chapters – have become institutionalised. This institutionalisation limits imaginative thinking and the development of new ideas, which consequently restricts changes that could improve the management of conflicts. For instance, Scott (2014) argues that actors who are embedded within institutions have difficulty in changing them because they are, to some degree, institutionalised themselves. As Figure 8.3 demonstrated, the actors responsible for developing ideas are themselves institutionalised and thus influenced by existing, organisationally-embedded ideas. Their understandings of COIs are informed by the existing policies and guidance, which they in turn reproduce. In this way, these ideas become objective reality (Tolbert and Zucker, 1996), with particular understandings of COIs (such as what type of COIs are problematic and thus require management) being unquestioned and accepted as facts, making it difficult for new ones to be fostered.

However, some theorists have considered the ways in which change can occur. For example, Oliver (1992), Tolbert and Zucker (1996), Dacin et al. (2002) and Scott (2014) discuss the concept of deinstitutionalisation: the process by which existing institutional norms and practices are delegitimised, weakening and discontinuing as a result of challenges to, or failings of, existing ones. This results in change occurring, with new forms emerging. Zucker (1988) argues that entropy in social systems is the normal condition: organisations typically tend towards disorganisation, with roles and routines constantly being modified, thus causing ideas to break down over time. However, certain conditions must be met for the equilibrium to be upset and deinstitutionalisation to occur, such as a lack of demonstrable results associated with a structure (Tolbert and Zucker, 1996). Oliver (1992) offers a framework (see Figure 8.4) for the predictive and moderating factors that can cause institutionalised practices to become deinstitutionalised: political, functional and social pressures are external factors that are determinants of deinstitutionalisation, while inertial

and entropy are inherent pressures competing within the institution to maintain or destabilise the norms.

Figure 8.4: Pressures for deinstitutionalization

Figure 1  
Pressures for  
Deinstitutionalization



(Oliver, 1992, p. 567)

Several theorists have argued that in order for change to occur, actors within the institutional environment need to become aware of the limitations of existing practices and the need to develop alternatives (Scott, 2014, Mahoney and Thelen, 2010). Peters (2012) suggests that this could happen if one or more actors within an institution finds that their interests are not being advanced through their participation in the institution, and therefore opens themselves up to the possibility of change. Scott (2014) suggests that change might not only be achieved by those actors within the institutional environment recognising weaknesses with existing rules, norms and procedures, but that it can also be triggered by new actors entering the scene. Furusten (2013) agrees, and further writes that those advocating change need to acquire positions of legitimacy within the institutional environment and work within the circles where ideas are formulated, rather than attempting to affect change from the outside; they also need to mobilise others within the institutional environment to join them. These arguments indicate that while ideas may seem to be relatively fixed within institutions, it is possible for them to be destabilised and altered by those within them, providing they are able to recognise the weaknesses in existing ideas. In the context of this thesis, if actors working within the medical journal publishing institutional environment (such as publishers and journal editors), or new actors entering it, are able to recognise that current understandings do not allow COIs to be managed as effectively as is necessary, and are able to present themselves as legitimate actors to their colleagues so that their arguments are listened to, then it may be possible for new ideas to be generated.

Schmidt (2008b, 2010b, 2010c, 2008a) developed the concept of Discursive Institutionalism (DI) to explain not only the stability of institutions, but also how they can change. DI focuses primarily on the ideas and discourses of individuals within institutions (rather than structures and hierarchies). Ideas are the result of interactions amongst the members. According to DI, these ideas in turn shape the definitions of actors' interests and behaviour, and thus constitute institutions (Campbell and Pedersen, 2001). While stable to some extent, they are also indeterminate and therefore can be renegotiated (Peters,

2012). DI therefore provides a framework to explain further the dynamics of both continuity and change within institutions, arguing that it is perceptions of crisis, together with the presence of alternative discourses amongst actors, that make change possible (Campbell and Pedersen, 2001, Hodgson, 2006).

Schmidt (2008b, 2010b, 2010c, 2008a) describes how institutions act as both constraining and enabling structures. Individual actors are an integral part of these institutions: their 'background ideational abilities' (their internal knowledge of how the world works) explain how they create and maintain those institutions, and their 'foreground discursive abilities' (their ability to think critically outside their institutions) enable them to communicate critically about the institutions, in order to either maintain or change them. Schmidt discusses two ways in which ideas are communicated in relation to institutions. The first is her concept of 'coordinative discourse', which refers to the discourse between members within an institution as they develop ideas; these are open and interactive (Peters, 2012). Some individuals may be more influential than others, depending on their persuasive abilities or perceived knowledge (Ibid). The second concept is 'communicative discourse', which is the discourse used by individuals and groups in presenting their ideas to the wider public.

While Schmidt acknowledges that most ideas and discourse tend to support existing realities, rather than promoting change, she argues that, by examining the 'foreground discursive abilities' of actors, one can investigate and understand how change might occur (or why it does not). In DI, the institution is dependent on ideas being imported into it, and thus is always potentially open to new ideas (through actors' foreground discursive abilities). The status quo only exists in the short term, with older definitions of problems and solutions potentially being outmanoeuvred by, or (more likely) combined with, new ones. The latter is achieved through the process of bricolage, whereby elements from existing ideas that are already at hand, as well as ones that have formed elsewhere, are combined to form innovative ideas (Carstensen, 2011, Schmidt, 2010a, Campbell, 2005). Bricolage 'may entail the rearrangement of elements

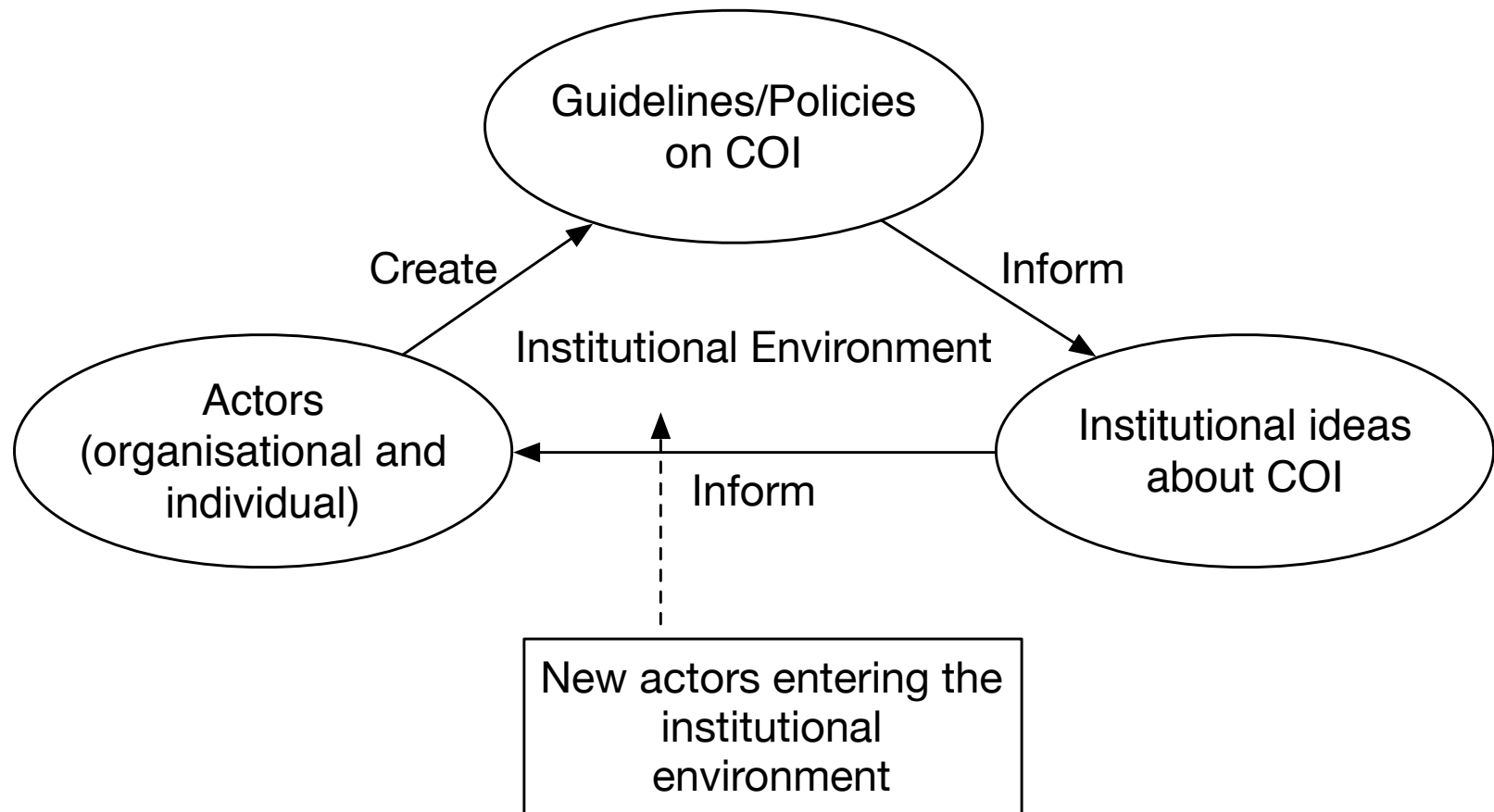
that are already at hand, but it may also entail the blending in of new elements that have diffused from elsewhere', resulting in, 'an innovative recombination of elements that constitutes a new way of configuring organizations, social movements, institutions, and other forms of social activity' (Campbell, 2005, p. 56).

Schmidt's work applies DI in a political science context. However, this theory can also be employed in the context of this thesis, to explore the possibility (or failure) of changing the ways in which COIs are conceptualised and managed in medical journal publishing. While Chapters Five, Six and Seven demonstrated an institutionalisation regarding this topic in medical journal publishing (with a narrow understanding that focused on authors' conflicts, financial interests and disclosure), as discussed in this section, it is possible for institutionalised ideas to change. Currently, those involved with the development of new policies and guidance on COIs are part of the existing institutional environment, and their ideas are informed by pre-existing ones. However, new actors frequently enter the institutional environment of medical journal publishing at various points (such as new journal office staff, editors in chief and publishers). While they will be informed by existing institutional ideas (and they may face some opposition to change from those who benefit from the status quo), they can potentially bring fresh perspectives, which may either merge with current ideas or replace them (see Figure 8.5). In addition, drawing on the knowledge of actors who are critical of, and have conducted research on, the industry (such as those interviewees listed in this thesis under the category of medical publishing critics) and involving them in discussions would allow new ideas to be developed. Through the collaboration of actors using their foreground discursive abilities to think critically about their institutions, it may be possible to develop new ideas regarding COIs.

Chapter Seven looked at a number of existing additional initiatives that assist in the management of COIs in medical research and publishing, such as CTR, CTP and Reporting Guidelines: while these do not yet appear to be fully

utilised or successful in regulating COIs, they do demonstrate an ability to consider and develop new ideas. An example of a new idea emerging through the process of bricolage, which offers the alternative to journals requesting and managing disclosures, is that of a central database to house such information, as discussed in section 7.3.1 of Chapter Seven (and which will be examined further in Section 8.5.2 of this chapter). This combines elements of existing processes: the policy of disclosure and the idea of a repository that contains information on researchers (such as ORCID – see Section 7.3.1 of Chapter Seven).

Figure 8.5: New ideas entering the institutional environment of medical journal publishing



(Original diagram.)



#### **8.4.1 Reimagining conflicts of interest**

The following section looks at some suggestions that emerged through this research, which could result in smaller, more incremental changes, as described by Mahoney and Thelen (2010) in the conceptualisation of COIs and their management. It focuses on redefining and broadening understandings of COIs. As discussed in Chapter Five, the current conceptualisation of COIs is fairly basic and narrow. There is currently a focus on financial interests, commercial funding, and on authors as a conflicted actor group, with little attention given to other types of interest and actor groups. As previously mentioned, the latter may consequently remain unregulated, despite potentially having an effect on medical/health research and resulting articles. A wider understanding – both of what COIs are and who can be conflicted – might make it more likely that a greater number of conflicts would be considered when attempting to manage COIs. The suggested changes in this section are developed out of an analysis of existing understandings and based on weaknesses identified in the data.

The current construction of COIs focuses on financial interests, with limited interrogation of non-financial types. For example, the *BMJ* states that it only asks authors and reviewers to disclose financial COIs in the hope that this will lead to greater disclosure of those types of interest. In doing so, the journal has, in practice, largely discounted the relevance of non-financial COIs and their need to be managed. It may be harder for agreement to be reached over exactly what constitutes non-financial COIs, and for journal editors to check whether authors (and reviewers) have fully disclosed these kinds of interests (and for journal owners to investigate their editors' non-financial interests). However, this does not mean that they do not potentially have an influence on articles (Marcovitch et al., 2010, PLoS Medicine Editors, 2008) and that they should not be considered in understandings of COIs. This narrow focus is one characteristic of the institutionalization of understandings of COIs, which has perhaps developed because non-financial interests are harder to define and quantify than financial ones, and thus are more difficult to manage through disclosure.

However, as Davis (1993, 1982) and Friedman (1992) argue (see Chapter Two, Section 2.2), other interests besides pecuniary can affect people's judgement. Authors, reviewers and editors may all be affected by non-financial interests (such as career advancement or personal relationships) that could conflict with their primary ones, and thus cause them to be biased. Focusing only on financial interests reduces our understanding of what can lead researchers to be biased, and simply ignoring them, as per the *BMJ*'s policy, means that they will go unmanaged. The literature review in Chapter Two demonstrates these other sources of COI can motivate actors (Woll, 2008). For instance, studies show that, for example, interests such as career advancement can conflict with researchers' responsibilities to protect study participants (Levinsky 2002, Stell, 2010, Gieyrn, 1983) (see Chapter Two, Section 2.3.1).

There is some debate in the medical/health literature on non-financial COIs (Levinsky 2002, PLoS Medicine Editors, 2008), and limited research has been conducted into them in relation to medical journals (Viswanathan et al., 2013). While some interviewees were dismissive of, or unsure about, non-financial COIs, others did acknowledge that they too can be problematic. This demonstrates that there are actors within the institutional environment of medical journal publishing who are alert to the problems that they can pose, and therefore offer the possibility of change. Viswanathan et al. (2013) conducted a study on non-financial COIs, focusing specifically on systematic reviews, and provided several examples of non-financial interest that could represent conflicts: advocacy/policy positions, particular specialities that researchers are trained in that may bias them in favour of certain approaches, and professional relationships. *PLoS Medicine* has also produced a comprehensive list of examples of non-financial conflicts (see Chapter Five, Table 5.11), which other journals, publishers and professional associations could learn from. As a relative newcomer to medical journal publishing, and with a different funding model from the norm, *PLoS Medicine* (formed in October 2004) may be able to highlight weaknesses in current understandings, and bring more fresh, innovative ideas to the institutional environment. As a successful and respected journal with a

high IF, the ideas proposed by its staff may be considered by others. That said, the fact that the *BMJ*, another well-respected and high IF journal, has taken the conscious decision to sideline non-financial COIs, demonstrates perhaps how deeply ingrained this institutionalised idea that non-financial interests are less significant is, and the difficulty in substantially changing thinking regarding it.

The current conceptualisation of potentially conflicted actors within the medical journal publishing institutional environment focuses on authors, despite existing evidence demonstrating how other actor groups can have conflicts that affect journals (see Chapter Two, Section 2.3.1). While there is a heavy focus in policies and guidance on authors' COIs, with discussion and examples given for them, there is less offered on other actor groups' COIs. Information available in journals' 'Instructions for Authors' and submission processes understandably emphasises authors' COIs as it is this actor group at whom they are primarily aimed. However, an important step forward would be if they were to also offer information on contributors' COIs, as they too are involved in the development of articles, and as such, any conflicts they have could also could affect journal content. The fact that journals' 'Instructions for Authors' generally do not refer to these actors demonstrates the narrow, institutionalised conceptualisation of whose conflicts might affect articles. The sample journals' websites were analysed for policy documents on other actors' COIs, and as Table 5.3 in Chapter Five showed, while the majority of high IF journals do have information on editors' and reviewers' COIs, only five of my 'contentious cases' journals have any on reviewers, and only two on editors. After authors, the actors most focused on in the professional associations' and publishers' guidance were reviewers and editors, although there was variety in the quantity of information provided, and it was not always easy to locate. Of the professional associations, the publishing ones (CSE, COPE, ICMJE and WAME) discuss editorial independence, but do not provide any detail of why and how journal owners may be conflicted. Similarly, of the publishers, only Wiley and Elsevier have sections on editorial independence; again, these do not provide details of the COIs the owners themselves can face. This is despite discussion of these in the literature,

and several highly publicised incidents where editors were fired from high IF journals due to conflicting interests between them and their journals' owners (see Chapter Two, Section 2.3.1.2, and Chapter Seven, Section 7.2.2.3). There was also an absence in the guidance and policies of publishers' on medical writers' potential COIs, and of the professional associations, only AMWA, EMWA and ISMPP (specifically targeted at medical writers) mentioned them. There was a notable lack of discussion in journals' guidance and policies regarding medical writers, even amongst those that have been involved in high profile cases involving them (see Chapter Two, section 2.4). This is surprising, as one might expect that journals that have been criticised for their employment of medical writers would ensure that they have robust policies surrounding this actor group. Similarly, the failure of some high IF journals to make reference to medical writers' potential COIs is notable, due to these actors' controversial role (Sismondo, 2009, Sismondo and Doucet, 2009, Sismondo and Nicholson, 2009, McHenry, 2010, Moffatt and Elliott, 2007, Hendrick, 2011).

There was also less talk of actors other than authors in the interviews (see Chapter Five, Section 5.2.2): while all 48 interviewees discussed authors, only 26 talked about editors and 21 about reviewers. Seven referred to medical writers, while only two talked about statisticians and two about contributors in general. The fact that half of the editors in chief interviewed (three out of six) did not broach the matter of editors' COIs demonstrates a lack of awareness of how they themselves might have conflicts that could affect their journals. This is perhaps a result of their 'blind spots', as discussed by Pronin (2004) (see Chapter Two, Section 2.2), and is concerning as it means any conflicts they have may remain unmanaged. This limited focus was also shown in interviews with those categorised as 'medical publishing critics': all six mentioned authors, and four talked about editors, but only one referred to reviewers and one to medical writers. This interview data reflects an institutionalised way of thinking about COIs that is resistant to change, as referred to by Powell and DiMaggio (1991) (see Section 8.3), so much so that even those representing critical voices are restricted to concentrating primarily on those actors that have come to be

understood as the conflicted group. Ideally, more focus should be given to other actor groups, so that appropriate means to manage them might be developed. Given the fact that understandings remain limited, despite there being demonstrable results which show how other actor groups' conflicts are problematic, and that even the critical voices appear to be institutionalised in this regard, for change to occur, rather than it being brought on incrementally by critical actors (Schmidt, 2008b, 2010b, 2010c, 2010a, Tolbert and Zucker, 1996), perhaps a more endogenous shock is required (Hannan and Freeman, 1984, 1989). Alternatively, new actors who enter the institutional environment and are able to look beyond current ideas and be listened to by those already there may be able to affect change (Scott, 2014, Furusten, 2013).

#### ***8.4.2 Reimagining disclosure***

Chapter Six shows that disclosure is currently the main mechanism through which COIs are managed in medical journal publishing. The sample guidance and policies all refer to disclosure when discussing COI management, without offering any other suggestions; the reliance on disclosure was further reflected in the interviews. There are benefits to the process of disclosure, as we saw in Section 2.5.1 of Chapter Two and Section 6.4.1 of Chapter Six: for example, it is a low-cost solution that requires no considerable changes, offers transparency and possibly improves honesty and trustworthiness (Church and Kuang, 2009, Fontanarosa et al., 2005). Loewenstein, Sah and Cain (2012) argue that the question should not be as to whether or not to disclose, but rather how to ensure that disclosure has its intended effects. They suggest that, to the extent that disclosure works, it is typically through influencing the behaviour of those whom the disclosure is about, rather than those to whom the disclosure has been made. Disclosure arguably forces actors to be more reflexive and consider how their relationships, both pecuniary and non-financial, may have biased them.

Section 2.5.1 of Chapter Two, and Section 6.4.2 of Chapter Six, however, highlight some of the weaknesses of disclosure: for example, it is often difficult

to recognise bias in ourselves, and we therefore may not recognise an interest as representing a conflict (Cain and Detsky, 2008, Pronin et al., 2004, Dana and Loewenstein, 2003). Disclosure may cause people to act in a more self-serving way, or over-state advice (Cain and Detsky, 2008, Kassirer, 2009a, Jamal, 2012, Loewenstein et al., 2012). Therefore, if the disclosure process is to be so heavily relied on, it requires improvements. Disclosure depends greatly on the honesty of those disclosing, which was cited by interviewees as a deficiency of the process. Editors rely on authors to be honest, and authors in turn have to trust their co-authors; editors also have to believe their reviewers to be honest, and readers have to assume that the editors of journals are not allowing any conflicts they have to affect their behaviour. Yet authors (and other actors) may be reluctant to disclose for various reasons, not all of which are necessarily suspect. As Thompson (1993) argues, having COIs is purely situational and they are not in themselves an ethical failing: COIs, while universal, have a pejorative connotation, and as such authors may withhold information out of fear that readers will automatically doubt their research (Rothman, 1993). While some critics have called for a ban on authors with conflicts from submitting articles to journals, this is therefore perhaps a reductionist and unworkable proposal. For example: the conflicts may not have impacted on their research and writing; it may be important research that should be published; and such policies may force authors to simply hide their conflicts. However, such conflicts are still problematic as they pose the *risk* of bias (Carson, 1994, Friedman, 1992, Luebke, 1987), and therefore require effective management. Smith (1998) suggests that rather than attempting prohibition, the focus should be on adequate transparency. Linking back to Section 8.4.1, in order to make the process of disclosure more effective, perhaps the very way in which COIs are conceived needs to be rethought so that there is less focus on the negative implications of conflicts, and more understanding of the fact that they are simply a state of being: true objectivity is difficult, if not impossible, to achieve.

While self-disclosure is currently the main method for managing COIs, as discussed in the previous section, there is a limited conceptualisation of who can

be conflicted; thus, as it stands, many actor groups do not have to disclose. Although professional publishing associations, such as COPE, WAME and ICMJE, do advise that journals request disclosures from editors and publish them, they offer fairly limited further guidance on how this information should be obtained or managed. Other than Wiley, there is scant advice provided by the publishers. As Chapter Six shows, few journals publicly disclose their policies on editors, nor do many publish their COIs. All of the professional associations say that reviewers should be required by journals to declare any COIs when asked to review; however, none of my sample publishers offer effective guidance to their editors on this, and it generally appears to be an informal process by the journals, with a lack of clear published policies. The lack of detailed and effective guidance on these actor groups in all the sample policies/guidance demonstrates an institutionalised way of thinking which focuses on authors' disclosure. This is despite the fact that, as shown in Chapter Two, Section 2.3.1, editors' and reviewers' COIs can impact on the content of journals.

Ideally, recognition of the need for editors and reviewers to disclose should become common practice throughout medical journal publishing, with formal policies developed that will ensure their conflicts are effectively and transparently managed. For example, as ICMJE and COPE advise, public disclosure of any relevant interests on the part of editors (for example, on the journals' websites) should be a component of such policies, as should disclosure of journals' revenue streams on their websites (as recommended by COPE and CSE). This would be a positive step forward in terms of improving transparency more broadly. However, having such policies, of course, is only of use if they are put into practice: as discussed in Chapter Six, Section 6.3.2 regarding the case of Jeffrey Drazen, editor in chief of the *NEJM*, the journal did not follow its own policy in appointing him (New England Journal of Medicine, 2016, Charatan, 2000, Gottlieb, 2000, Gottlieb, 2002, Steinbrook et al., 2015). The *NEJM* is an influential, high IF journal and a member of the ICMJE, and as such will hold a strong position in the generation of policy ideas through coordinative discourse (Schmidt, 2008b, 2010c, 2008a), but if such key actors do not uphold their own

policies, it is unlikely that they can be relied on to encourage and instigate change. Instead, for it to occur, new critical voices to the institutional environment are perhaps required, as suggested by Scott (2014) and Furusten (2013).

Currently, in most cases, only those listed as authors have to disclose conflicts on articles. Those who meet the authorship criteria (in most cases these are the ICMJE's (1985)) are understood and accepted to be potentially conflicted actors; those who do not quite meet them are not. This is despite the fact that, as contributors, they may have had a significant role in the research or development of an article (such as medical writers and statisticians), and may have conflicts that could have affected it. Ideally, the potential conflicts of all those involved in an article should be disclosed. To capture this, perhaps the definition of authorship needs to be widened. Yet despite on-going criticisms that have been made of the ICMJE's authorship criteria (e.g. Matheson, 2011, Moffatt, 2013, Helgesson, 2015, Bennett and Taylor, 2003), they are still the most commonly used by medical journals. The ICMJE, as was discussed in Chapter Three, Section 3.3.1, is made up of only a small number of high IF, influential journals, and is a powerful organisation within the institutional environment of medical journal publishing. Its general rejection of criticism of its authorship criteria, and their continued use by the majority of medical journals, reflects the institutionalised culture surrounding authorship. Again, for change to take place, critical thinkers are required to advocate alternatives, as well as for figures within the current institutional environment to recognise the weaknesses of the current processes and being willing to adopt new ones.

Another alternative to changing authorship criteria would be for journals to move to a contributorship model, as first discussed by Rennie et al. (1997) (see also Yank and Rennie, 1999, Davidoff, 2000, Smith, 2012). The *BMJ* has followed these recommendations: along with listing authors who meet the ICMJE's criteria, it requires lists of contributors, with details of what they did (though it is not clear as to whether they have to complete a disclosure form or



not), and a guarantor who accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish (British Medical Journal, 2016a). Requiring disclosures from all contributors to a manuscript (including what their role was, who funded them, and any other potential conflicts) would offer readers more information and allow them to assess the articles within this context. Only six of my sample journals state that contributors (and/or medical writers) should be listed in the acknowledgements of an article, with their funding (and sometimes other financial disclosures) listed; only three journals ask for all of contributors' potential COIs. Medical writers interviewed argued that they should not have to disclose their COIs as they work only with what is provided to them by the authors, and they therefore are not in a position to introduce bias into a manuscript. This may be true if they are simply editing an article; however, if they have any influence over how content is structured and framed, then they are in a position to introduce bias, and evidence shows that some (industry-funded) medical writers have previously behaved unethically and been involved in developing articles that misrepresent the products under discussion (see Chapter Two, Section 2.4). It therefore seems that requiring disclosures from these actors can only be beneficial in attempts to provide more transparency. However, while the idea of a contributorship model was first suggested almost twenty years ago, it has not in general been taken up by medical and health journals, much to the frustration of its proponents (e.g. Smith, 2012). This is an example of the institutionalisation of an idea. It has become fully sedimented, and despite attempts by critics to alter it, a general inertia makes it difficult to achieve change.

The requirements for authors' disclosure vary across journals, both in terms of what they should disclose, and how they should do so. Of the professional associations, only the ICMJE provides advice on how this should be done. Journals appear to have autonomy in terms of setting their policies, and analysis shows that these are not always as stringent as those which are recommended by their publishers. There may therefore be benefits to be drawn

from publishers being more insistent on particular practices being followed as part of the condition for publication (and in the case of publishers such as Springer, Oxford University Press and Taylor and Francis, they should actually provide more detailed advice). The data analysed suggests that it would also help if the owners (publishers or societies) provided more resources both to educate actors and to enable editors to more thoroughly check disclosures from authors.

Loewenstein et al. (2012) suggest that disclosures 'could be made more effective, less burdensome and more complete by creating a unified web-based universal online disclosure form, by storing and making available detailed explanations about payments received ... More comprehensive and uniform disclosure should make it more likely that physicians will be discouraged from entering into problematic conflicts because of the threat of having to clearly disclose them' (p. 670). Chapter Seven, Section 7.3.1 looked at the idea of a central repository, as raised by 11 interviewees, where disclosures could be stored. This is an example of actors using their 'foreground discursive abilities' (Schmidt, 2008b, 2010b, 2010c, 2010a) to develop new ideas based upon existing ones, through the process of bricolage: the idea of disclosure and central repositories containing information is combined to produce an alternative to the current system whereby journals request and manage disclosures. These interviewees argued that a central repository which contains information on actors' interests, working in conjunction with statements on manuscripts, would have many benefits. It would save journals time, as they would not have to request disclosure forms from each author: they could simply ask for their database IDs, although ideally they would still check the database entries against that which had been declared on the manuscript (so would still require the resources to do this). It would also benefit authors as they would not have to complete different forms in varying formats, with changing requirements each time they submit an article to a different journal (although they would have to keep their profiles updated). Further, it would present readers with a bigger, broader picture of what might have influenced authors (a link should be

provided in articles to the author's entry in the repository). Other actor groups, such as editors, reviewers and contributors (including medical writers) could also have profiles on the database. It could be expanded and amalgamated to include other information such as CTPs and CTRs.

Five interviewees (a publisher, a medical writer and three managing editors) suggested that ORCID, a database launched in October 2012 that links research activities and outputs to researchers (see Chapter Seven, Section 7.3.1), could perhaps be expanded to fulfil the role of such a COI database. Another interviewee referred to databases such as PubMed (managed by the U.S. National Library of Medicine, and specific to medical literature), Scopus (owned by Elsevier) and Web of Science (owned by Thomson Reuters). Regarding the financing of such an initiative, if a standalone repository for COI data was developed, interviewees suggested that it could perhaps be paid for by publishers, funders (both commercial and public), researchers' institutions and/or companies such as those employing medical writers. Another option would be to charge an annual fee from users to have a profile (with discounts given, for example, to independent researchers or those in developing nations). Professional bodies/societies and employers could insist that their members/employees sign up. It would be possible to have legal policies in place that require researchers to join, but this could only be done on a country-by-country basis. Perhaps the most effective means of ensuring up-take would be for journals to insist on users having profiles as a condition for publication, and publishers could require their editors to have them. The professional associations, such as ICMJE, COPE, CSE and WAME could also endorse such a database. A system such as this would, in theory, have the potential to streamline the disclosure process.

#### ***8.4.3 Reimagining data access***

Eleven interviewees from across the actor groups in my sample brought up the idea of making raw research data more accessible. While this would not prevent

researchers and their funders from suppressing data, these interviewees argued that it would generally improve transparency and accountability, allowing others to look at the data upon which articles and their conclusions are based. Data could be made available to journals, or to the wider public. In the case of the former, they argued that journals could employ independent statisticians to analyse the data, and thus it would encourage authors to be more careful about how they portray their results. A limited number of journals do already require the data from submitting authors; if professional associations and publishers insisted on it, it may become more common and therefore effective (though, as discussed in Chapter Seven, in relation to CTR and CTP, endorsement by professional associations does not always result in this). This would only work, however, if there was a unified approach by the journals; as discussed in Chapter Five, *JAMA* has ceased to independently analyse data due to the fact that (according to an interviewee from the journal) they were losing commercially-funded papers. Further, it would depend on journals having the resources available to employ such people: while large, well-resourced journals such as those in my high IF sample may be able to afford this, smaller publications, such as those represented in my 'contentious cases' sample, may not be in the position to do so. Two medical publishing critics interviewed also argued that making data publicly available to the wider public would enable others to reanalyze and re-author papers, and again make authors more careful about how they represent their data.

Some initiatives do already exist in this area. For example, ClinicalStudyDataRequest.com is a collaborative effort, started initially by GlaxoSmithKline and now supported by 13 pharmaceutical companies (ClinicalStudyDataRequest.com, 2016c). Through it, researchers can request access to data and perform further studies on it (ClinicalStudyDataRequest.com, 2016a). In 2016, the ICMJE published proposals for journals to require anonymised data no later than six months after publication (Taichman et al., 2016). The YODA Project by Yale University (Krumholz et al., n.d.) seeks to develop an independent model (unlike Clinicalstudydatarequest.com which has

been developed by pharmaceutical companies) for sharing clinical research data. The European Medicines Agency (EMA) adopted a policy on the 1<sup>st</sup> January 2015, whereby clinical trial data involved in approved medicines should be published once marketing authorisation is complete (European Medicines Agency, 2014, European Medicines Agency, 2015b). The *BMJ* runs an 'Open Data' campaign, documenting its coverage of adverse outcomes associated with hidden clinical trial data, and recording pharmaceutical products for which the absence of complete clinical trial data has caused a misrepresentation of the evidence base (British Medical Journal, 2016b).

Although the interviewees who advocated the making of data public did not discuss it, this proposal entails issues regarding the confidentiality of data (Pisani et al., 2010, Ebrahim et al., 2014, Walport and Brest, 2011). However, the initiatives discussed above have attempted to develop methods to manage this. The EMA addresses the issue of participant confidentiality in clinical trials by stating that it will not make personal trial data public or include it in the database, and will respect patients' informed consent (European Medicines Agency, 2014, European Medicines Agency, 2015a). Clinicalstudydatarequest.com requests that users sign a data sharing agreement that specifies that they will protect the privacy and confidentiality of research participants (ClinicalStudyDataRequest.com, 2016b).

Another risk is the potential for data to be misinterpreted by those conducting secondary analyses, either intentionally or inadvertently (Henry and Fitzpatrick, 2015, Ebrahim et al., 2014). Also of concern is that researchers in resource-poor areas who generate much of the public health datasets, will lose out to their counterparts in better-resourced countries, who have the skills and tools to analyse and publish from them (Walport and Brest, 2011, Pisani et al., 2010). It is also questionable as to whether manufacturing sector companies would be truly willing to render their data public. While some pharmaceutical companies are making data available, this is through ClinicalStudyDataRequest.com, a site run by the 13 participating companies. The

initiative is limited as the companies are not providing data involving off-label use of drugs, and the cut off date for some of the companies is fairly recent (for example, Sanofi is only providing data from January 2014). This means that data from trials before this will not be given (Silverman, 2014). There are also concerns about patient data owned by the government – such as ‘real-world data’ gathered by the NHS – being made available to manufacturing sector companies for their own commercial gain (there are anxieties about patient confidentiality entailed in this as well) (Fischer, 2012, Ramesh, 2014).

Such moves towards greater data accessibility, together with the fact that 11 of my interviewees discussed it, demonstrates at least a partial awareness amongst institutional actors of the weaknesses of existing processes (Mahoney and Thelen, 2010). These initiatives demonstrate the possibility of new ideas entering the institutional environment through members’ critical thinking – their foreground discursive abilities (Schmidt, 2008b, 2010b, 2010c, 2010a).

#### ***8.4.4 Reimagining funding models***

As discussed, change in an institution (or institutional environment) can arise through critical voices, which can generate new ideas (Schmidt, 2008b, 2010c, 2008a, 2010a). Two medical publishing critics, interviewed for their critical and analytical opinions, suggested alterations to the ways in which medical and health research funding is managed and distributed. They argued that for effective improvements to be made in the management of COIs in medical/health journals, fundamental alterations to the models of publishing and funding of research are required. One idea proposed was that, rather than manufacturing sector companies directly hiring researchers to conduct the work, the money could instead be paid to independent funding bodies, which would then distribute the funds. This would require measures to ensure that the funding administrators remained independent, which may be difficult to achieve: for example, their jobs would be reliant on these companies continuing to provide funds. It is also questionable as to whether it would prevent researchers from

being conflicted: they would still be aware of the source of their funding, and may be wary of producing research that is critical of that source's products. Further, it may be difficult to get companies to subscribe to such a system, unless they stood to benefit in some way.

Previous experience in connection with the tobacco industry has shown that such measures are not always successful. The establishment in the UK of the Health Promotion Research Trust, which channelled funds from the tobacco industry to a supposedly independent trust, which then administered them (UK Parliament, 1983), was criticised by some public health researchers who argued that those in receipt of the funding would still be, to some extent, beholden to the tobacco industry (see Chapman, 1987). While the researchers may or may not have succeeded in remaining independent, their work would be subject to concerns about bias; indeed, one Professor, Hilary Rose, returned £30,000 to the trust after considering the implications of how his research, funded in this manner, would be perceived (*ibid*). Furthermore, the Trust specified that research funded by the trust should not include studies that directly or indirectly examined the use and effects of tobacco products, thus indicating that the trust itself was not truly independent (Chapman, 1987). In the US, the Master Settlement Agreement (MSA) of 1998 (U.S. Government, 1998) required that key tobacco-funded initiatives ceased (The Center for Indoor Air Research, The Tobacco institute and The Council for Tobacco Research), resulting in the tobacco industry's loss of a crucial connection to academics and the private sector (Schick and Glantz, 2007). It also required participating tobacco manufacturers (which were involved in litigation against several U.S. states) to contribute to a Foundation, the aim of which was 'to support (1) the study of and programs to reduce Youth Tobacco Product usage and Youth substance abuse in the States, and (2) the study of and educational programs to prevent diseases associated with the use of Tobacco Products in the States' (U.S. Government, 1998, section VI). The MSA had some success in tobacco-control efforts, such as the disclosure on the internet of previously secret tobacco industry documents (Givel and Glantz, 2004). However, the success of it in relation to funding of

research by the tobacco industry has been questioned. Since the MSA, individual tobacco companies in the US have simply replaced their collaborative funding organisations with individual research programmes. These programmes have funded organisations that have downplayed or hidden their connection with the tobacco industry, despite having key members with significant, long-standing relationships with it (Philip Morris through the Life Sciences Research Office, and British American Tobacco through the Institute of Science and Health) (Schick and Glantz, 2007).

These experiences from the tobacco industry thus demonstrate that if such a scheme were to be implemented to channel medical research funding from manufacturing sector companies, its design and administration would require careful consideration. For example, there would need to be sufficient mechanisms in place to ensure that the funding administrators themselves were, and remained, independent, and that there were provisions in place to guarantee that those in receipt of such funding used them appropriately. While they may be difficult to establish, presenting such suggestions to those within the institutional environment of medical journal publishing may potentially prompt discussion (as Schmidt (2008b, 2010b, 2010c, 2010a) refers to it, ‘coordinative discourse’) and allow new ideas involving some elements of them to emerge.

## **8.5 Directions for further research**

This chapter focused on how ideas surrounding COIs and their management are narrowly imagined and have become institutionalised. This is limiting as only certain types of interests by particular actors are being actively managed, through the process of voluntary disclosure (not necessarily the most robust means of managing COIs). The institutionalisation of this narrow way of thinking about COIs makes it difficult for alternative approaches to gain traction. Through analysis of the data, several ideas have been proposed in this chapter of how these existing understandings could be adjusted in order to achieve more effective regulation of COIs.



The following section looks at several areas identified in this research that warrant further research. The first suggestion is for more research into non-financial COIs: what sorts of interests, other than financial, can represent conflicts for those actors within the institutional environment of medical journal publishing, and how these might be managed (Section 8.5.1). The second avenue for further research is into the development of a central database that holds COI information (Section 8.5.2). This idea is based upon the process of disclosure, and thus represents a more incremental change to the existing system. The two other ideas that would benefit from further research – increased data access and alternative funding models (Sections 8.5.3 and 8.5.4) – are more radical, and challenge current institutionalised thinking. These suggestions would not prevent all types of COIs from potentially affecting research (such as individual researchers' personal COIs, or editors' and reviewers' COIs), but may assist with those that arise from funders' influence over research. For these ideas to be taken forward and considered, a shift is required in current institutionalised ideas, which is perhaps unlikely given the various interests that are vested in the status quo, and the tight ties between clinical research and the pharmaceutical industry (Sismondo, 2008a). However, it would be beneficial to investigate in greater detail how they could be practically implemented, in order to more effectively manage potential COIs in medical research and publishing.

### ***8.5.1 Non-financial conflicts of interest***

The principal focus regarding COIs in medical/health research and journal publishing is financial relationships. This was demonstrated in the existing literature (see Chapter Two), and it was also reflected in my empirical work. As such, the results of my analysis have inevitably centred on these types of interest. However, my research did find that non-financial COIs can also be problematic (Levinsky 2002, Saver, 2012, Marcovitch et al., 2010, PLoS Medicine Editors, 2008), but that currently there do not appear to be sufficient mechanisms in place to manage them. Thus, one avenue for further study would be into non-

financial COIs. Currently, only limited research on this issue within medical/health journal publishing appears to have been done, and more evidence on how non-financial COIs can effect journals is necessary (PLoS Medicine Editors, 2008). Further investigations into the types of (non-financial) interest that could potentially constitute a conflict, the impact they can have on academic journals, as well as how they could be managed effectively, should also be undertaken. Viswanathan et al.'s study (2013) does look at non-financial interests, but it focuses specifically on how they could be managed in systematic reviews: research is needed on how they can be managed on other types of articles, as well as with other actor groups besides authors.

#### ***8.5.2 A repository for disclosures of conflicts of interest***

Several of the ideas for change examined in this thesis would benefit from further investigation into how potential COIs in medical research could be more effectively handled, to limit their impact on decisions (such as policy and prescribing ones) based upon publications. For example, as discussed in section 8.4.2, one suggestion that emerged from interviews regarding how COI disclosures could be more effectively managed was the development of a secure, online, central database where information on researchers' interests could be stored. When submitting articles, authors could provide editors with their database numbers, together with summary statements in their manuscripts of particularly pertinent interests; similarly, reviewers could provide editors with their database identifiers along with informing them directly of specific conflicts. Publishers could request this information from editorial staff and make it accessible on their websites. Existing databases containing information on researchers such as ORCID could be usefully considered for expansion to this end.

Further research should be undertaken into how such a system might be set up in practice, and how effective it would be in assisting in the management of disclosures. Along with learning from other repositories that manage COI

disclosures, such as ‘Open Payments’ on the Centers for Medicare and Medicaid website (Centers for Medicare & Medicaid Services, n.d.), the approach to this should be participatory, with the involvement of key actors working within the institutional environment of medical journal publishing (such as editors and researchers) who would be able to offer valuable insights as to how such a database could be best structured to ensure it is user-friendly. This would result in a greater chance of uptake of any such system that was developed.

### **8.5.3 Open data**

The concept of access to raw data perhaps lies at the heart of the problem of COIs in medical/health research and publishing (with regards to the COIs of researchers and funders): if access to raw study data was made available, it would greatly help prevent the problems associated with publication bias (see Chapter Two, Section 2.3.3) (Gøtzsche, 2011). If journals obtain the data, they could then employ independent statisticians to review it (although this would be dependent on their having adequate resources). Analysis of my sample journal guidance demonstrated that, to date, only *JAMA*, the *BMJ*, *The Lancet*, *PLoS Medicine* and *JNCI* require raw data to be made available to the journal upon request. While initiatives such as ICMJE’s proposal for data sharing (Taichman et al., 2016) are encouraging, as shown in Chapter Seven, Section 7.3.2, their support of other initiatives such as Clinical Trial Registration has not been that effective so far. Although it is necessary to have the buy-in of influential professional associations such as ICMJE, on its own it does not appear to be enough. As discussed, there are issues surrounding journals’ resources: many would not be able to employ independent statisticians to analyse the raw data of every study they publish. And journals that do so may experience resulting pressure from manufacturing sector companies. In 2013, *JAMA*, a well-resourced journal, ceased to use independent statisticians (Bauchner, 2013, McCarthy, 2013) (see Chapter Five). The official reason given by the journal was that alternative measures such as clinical trial reporting guidance and clinical trial protocols negated the need for journals to independently review data; however,

one interviewee from *JAMA*, suggested that it was in fact because the journal was losing industry-funded papers. Further, the fact that there are campaigns for greater data access, such as the *BMJ*'s (2016b), indicates that these mechanisms are not considered sufficient, and that there is a need for greater data access. However, increased data access would probably only be successful if all journals required it (this would at the very least require backing from the professional publishing associations) and ideally had the means to analyse it, for example, if the sponsoring companies provided them with the funds to do so. Alternatively, even if they did not analyse every article submitted, having access to the data of studies published would at least mean that, should concerns over data integrity arise, they would be able to conduct investigations (Steinbrook and Kassirer, 2010). The practicalities of how to implement such a system – for example, how to get journals universally to agree to participate, how to finance it, and how to manage the data and ensure confidentiality is maintained – appears to be a worthwhile avenue for further study, ideally through participatory research involving funders, publishers and journals.

#### ***8.5.4 Developing and implementing an alternative funding model***

Chapter One, Section 1.2 looked at the emergence in the U.S. of concerns about COIs in medical and health research: collaborations between the tobacco industry and researchers have been a concern since the 1950s; more recently (since the 1980s), such relationships between pharmaceutical companies and scientists have led to unease regarding the independence of ensuing publications (see Korn, 2000, Sharpe, 2002, Resnik, 2000, Warner and Gluck, 2003, Thompson, 1993, Healy, 2004, Etzkowitz, 1990, Etzkowitz, 1989). In the U.K. the Robbins Report of 1963 demonstrated an understanding of the need for a protective barrier between funders and researchers to prevent political considerations and pressures from affecting research, stating, for example, that government funding to universities should be provided through an independent body (Committee on Higher Education, 1963). As in the U.S., however, such barriers have since broken down, with universities currently quite heavily

reliant on money from the private sector, and both the government and private industry can now provide funding without an independent intermediary, thus giving them the potential ability to control the research (Evans, 2001).

As explored in Section 8.4.4, one proposal made by two medical publishing critics was to alter the ways in which funding is channelled from manufacturing sector companies to researchers, which would provide a barrier between the sponsor and researcher. As Sismondo has argued, 'radical solutions are called for, that divorce the pharmaceutical industry from published research' (Sismondo, 2008b, p. 112). Similar to the suggestions made by the two medical publishing critics, Marcia Angell proposed the establishment, in the U.S., of an institute within the National Institutes for Health, that drug companies would be required to contribute a percentage of revenues to; this would not be linked to specific drugs (Angell, 2005). The institute would then administer these funds to independent academic researchers to conduct drug trials, analyse the data and write the papers. She acknowledged, however, that the administration of such a system would have to be given careful thought. As discussed, past experience from the tobacco industry makes evident the complexities inherent in setting up such a system, and the difficulties in successfully placing a barrier between companies and researchers to prevent influence from the former over data. Future research might usefully explore, through for example, the examination of funding in other fields and discussions with key stakeholders such as commercial and public funders, how a new funding model might practically be developed, whereby funds are fed through non-commercial, independent bodies, thus providing much needed distance between funders and researchers, protecting academic freedom.

## **8.6 Key implications of this research**

### ***8.6.1 Implications for medical journal publishing***

One of the main findings of this research is that there exists within medical journal publishing narrow, limited understandings of COIs, in terms of who

might have them, what they might be, and how they should be managed. The result of this is that COIs in both the research and publishing processes are not currently regulated effectively and thus they may continue to impact negatively on the literature. For this to change, there is firstly, therefore, a need for institutional understandings to be broadened so that a wider range of COIs may be captured and successfully managed. There needs to be greater education of actors working within the institutional environment of medical journal publishing on the topic, so that they become aware of how different types of interest can constitute a conflict, and the ways in which a plurality of actors (including themselves) might have conflicts that require management. While the heavily-relied-upon process of voluntary disclosure gives the impression that organisational actors are dealing with COIs, it is not in reality as effective as is required; for COIs to be more effectively managed, there also needs to be a recognition by those within the institutional environment of this, and the need for more successful methods to be developed. For this to happen, a discussion is required within medical journal publishing on the weaknesses of current disclosure practices is required, as well as regarding what alternatives could be developed. This should include consideration of what else could practically, but more fundamentally, be done to limit the impact of COIs on the literature, including how the current processes of medical research and publishing, with often close involvement of commercial companies, could be restructured to provide more distance between corporate funders and the output of their sponsored research. As influential actors within the institutional environment, organisations such as COPE, ICMJE, CSE and WAME could help to begin this process of rethinking ideas surrounding COIs, encouraging dialogue amongst actors in medical journal publishing. The suggestions made in Section 8.5 might provide a useful starting point for these discussions.

### ***8.6.2 Broader implications for public health policy***

The findings of this research also have implications for public health policy more broadly. As Chapter One, Section 1.2, explained, since the 1980s there has been

a marked reduction in public funding of medical/health research, and a concurrent rise in sponsorship by commercial actors, increasing the likelihood of potential COIs occurring. These concerns stretch beyond the pharmaceutical and tobacco sectors that were discussed in this thesis, to other sectors, such as the alcohol, food and chemical industries. Here too lies the possibility that COIs will arise from corporate involvement in medical/health research and their consequent impact on health policy. How the ever-growing involvement of private interests can affect evidence-based research, and the lack of effective mechanisms to manage such relationships between funders and researchers, is a matter of deep concern for public health, as the veracity of the research that is produced is questionable. Research, that has been sponsored by companies with a vested interest in the outcome is likely to be biased. In lieu of an increase in public funding, efforts should therefore arguably be put into developing systems that separate corporate sponsorship of research from its outputs, such as those discussed in Section 8.5.4.

## **8.7 Strengths and limitations of the research**

This study offers an innovative and empirical insight into the topic of COIs within the institutional environment of medical journal publishing. Its key strength lies in the empirical data, in particular, the 48 original interviews that were conducted with actors working in a wide range of roles across the field. The author's own professional experience, acquired from working in the medical publishing industry, both prior to and while undertaking the research (discussed in Chapter Four, Section 4.2), helped her to gain access to these interview participants. Further, her own contextual knowledge of, and insights from, medical publishing, provide this thesis with a grounding in the industry under study

The interviews were conducted with actors working in a wide range of roles within the institutional environment of medical journal publishing. Through triangulating these with a large and comprehensive number of industry

documents, the data allows us to develop a detailed insight into how COIs are conceptualised in the field, and why such understandings surrounding them have developed and become institutionalised. As such, this study offers a new and important contribution to the public health literature. By demonstrating that an institutionalisation of ideas around COIs has formed in medical journal publishing, policy-makers will be better able to grasp the nature of the problem confronting them when making decisions based on the supposedly evidence-based research described within them. It is also hoped that it will bring the matter to the attention of those working within medical journal publishing, and help to prompt thinking as to how ideas regarding COIs might be reshaped and their management thus improved.

It may perhaps have also been interesting to conduct further interviews with participants out-with the institutional environment of medical journal publishing, so that an insight might be gained into how the issues uncovered in this research affects them and their trust in the medical/health research and publishing enterprise. For example, interviews could have been sought with those who use such journals to make decisions (such as doctors, policy-makers, or members of the public). This would have helped in developing an understanding of the further implications of the institutionalisation of ideas regarding COIs. However, the focus of this study, as stated in the primary research question (see Chapter One, Section 1.3), was on how the institutional environment of medical journal publishing informs actors' understandings of COIs, and this perhaps falls beyond its scope. It does, however, offer an interesting avenue for further study.

## **8.8 Concluding summary**

As Chapter Two demonstrated, much has been written on the topic of COIs in medical/health research and journal publishing. This includes studies on journal disclosure policies. This PhD advances this body of knowledge by offering an original qualitative study that draws on institutionalist theories to explore how



COIs are conceptualised, and their resistance to, and the possibility of, change. It offers readers an insight into the institutional environment of medical journal publishing, the actors within which have developed particular understandings of what COIs are, who might have conflicts and how they should be managed. These interpretations have developed over time and have gradually become institutionalised, understood as the 'external reality', making current approaches difficult to alter, despite some recognised weaknesses such as the fact that voluntary disclosure is dependent on the honesty of those disclosing. For the medical/health journal literature to be less affected by bias, COIs and their management need to be reconceptualised, to encompass a wider range of interests and actors, and allow more effective methods for regulating them to be developed. In this context, and drawing on theories of change in institutions, this thesis has examined the potential for new approaches regarding COIs.

The suggestion most often made for an alternative method to manage COIs was that of developing a central repository to store COI disclosure information (see Section 8.4.2). While this is still very much within the existing broad idea of disclosure, it may certainly help to improve the process. The two more deep-seated suggestions for change to enable COIs to be better managed, discussed in Sections 8.4.3 and 8.4.4, and further in Section 8.5, were Open Data and the development of a new model for funding. With regards to the former, despite various initiatives to encourage this, including ostensibly by the pharmaceutical industry, as shown by the *BMJ*'s campaign focusing on Statins and Tamiflu, this is not yet happening (British Medical Journal, 2016d, British Medical Journal, 2016e, Payne, 2012). Regarding the latter, experience from the tobacco industry illustrates that this would potentially be a complex solution, but it is certainly one that is worthy of further investigation. Habitualised behaviour (Hannan and Freeman, 1984, 1989, Jepperson, 1991) amongst the key actors that make up the medical journal publishing institutional environment may make the prospect of change occurring, in practice, difficult. The various actors comprising the institutional environment of medical journal publishing, and the perpetuation of ideas about COIs and their management, are interwoven. This

acts as a barrier to change, making it difficult for new ideas to enter and be considered.

However, as this thesis shows, some actors within medical journal publishing are considering alternatives, and therefore the possibility for processes to adjust does exist. While exogenous shocks may upset the equilibrium, it seems more likely that if change is to occur in medical journal publishing, it will be gradually and cumulatively over time, via endogenous elements (Mahoney and Thelen, 2010). This could occur through the encouragement of analytical reflection on existing understandings by actors within the institutional environment, as well as discussions with critical thinkers external to it (Furusten, 2013, Scott, 2014, Schmidt, 2008b, 2010b, 2010c, 2008a). Actors' 'foreground discursive abilities' and the process of bricolage may elicit new discourse and ideas (Schmidt, 2008b, 2010b, 2010c, 2008a). Examples where the critical thinking of actors has led to incremental steps towards changes in processes within medical research and publishing are the *BMJ*'s Open Data campaign (British Medical Journal, 2016b) and the AllTrials movement (AllTrials, 2014). In such a way, change and improvements to conceptualisations of COIs in medical/health journal publishing and their management might gradually occur.



## CHAPTER NINE: CONCLUSION

### 9.1 Summary of thesis

This thesis began, in Chapter One, by providing the contextual background to the topic that this research would address. It then outlined the aim of the research: to examine how conflicts of interest (COIs) are conceptualised within the institutional environment of the medical journal publishing industry, and what impact this might have on their effective management. Chapter Two continued by critically reviewing the existing literature of relevance to this topic, helping readers to further develop an understanding of it, and demonstrating the gap that this study helps to address. Existing research offers many examples of why COIs should be of concern, but it does not examine the concept of COIs within medical journal publishing in depth. The existing literature includes studies on disclosure policies in medical journals, which were discussed in this chapter. These quantitative studies are valuable in offering insights into these policies, such as who they target, how many journals have these policies in place, and how successful they are. However, they do not offer an understanding of the underlying context: of *how* the policies were constructed in this way and have come to be relied so heavily upon. Chapter Three provided a map of the institutional environment of medical journal publishing, thus offering a context through which to read the rest of the thesis, and to clarify the different actor groups that are referred to throughout it. Chapter Four reflexively discussed the qualitative methodological approach that was taken, including the research strategy, data sampling and analytical methods. The following three chapters (Chapters Five, Six and Seven) presented the empirical results. Chapter Five looked at how actors (both organisational and individual) conceptualise COIs: who is understood to potentially have conflicts that require management, and what types of interest can pose a conflict. It demonstrated that there is a heavy focus on the COIs of certain actor groups (particularly authors), while others, such as medical writers, are largely absent from the discussion. There is also an

emphasis on financial interests, while non-financial ones (often more complex) are considered far less. Chapter Six explored actors' understandings surrounding the management of COIs, and found that the process of voluntary disclosure is concentrated upon, with limited consideration given to other potential methods. Despite the reliance on this practice, it was acknowledged by some interviewees that there are inherent and serious weaknesses to it (the primary one being that it is reliant on the honesty of those disclosing); these, as well as interviewees' thoughts on disclosure's strengths, were examined. Chapter Seven investigated alternative methods of COI regulation. While some interviewees did refer to additional existing mechanisms that offer some potential to help better manage COIs, analysis showed that their uptake has so far been limited, and thus the reliance remains on voluntary disclosure. Chapter Eight proceeded to critically discuss these results in greater depth, engaging with theories of institutionalism to help to explain the findings, before offering some potential directions for future research (Tolbert and Zucker, 1996, Mahoney and Thelen, 2010, Schmidt, 2010b, 2010c, 2008a). This conclusion now returns the reader to the research problem posed in Chapter One, offering a summary of the findings in relation to it, and explains the contribution of this thesis to the literature.

## **9.2 Revisiting the research problem**

The aim of this thesis was to examine how COIs and their management are conceptualised by actors within the institutional environment of medical journal publishing. This required interrogating existing ideas and understandings that have been developed regarding whose COIs are perceived to require management in medical publishing, what types of interest can (and are perceived to) lead to COIs, how effectively COIs are currently managed and what alternative approaches are being put forward. In order to effectively explore this, the following research question was posed:

*To what extent does the institutional environment of medical journal publishing inform actors' conceptualisation and management of COIs and their consideration of alternative approaches?*

To answer this question, sample policies and guidance, along with the transcripts of 48 interviews conducted with actors working in a range of roles across the institutional environment of medical journal publishing, were thematically analysed.

The thesis argues that a particular way of thinking about COIs – who might have COIs that require management, what interests are particularly problematic, and how they should be handled – has become institutionalised and objectified within medical journal publishing. In other words, it is commonly accepted by actors working within medical journal publishing that particular types of interests can pose conflicts, and that they should be managed through the process of disclosure. This institutionalisation of ideas limits the imagination and makes difficult the exploration of alternatives, such as different methods of regulating COIs.

There is a focus on authors' COIs, financial interests and disclosure. While these are undoubtedly relevant (authors' COIs, and financial interests, do, of course, need to be effectively managed, and disclosure is a helpful tool in achieving this), there are also other actor groups (such as journal editors or medical writers) and types of relationships (for example, non-financial), which can also result in conflicts that may affect medical/health journals. The ways in which other actor groups, such as editors, reviewers and contributors might have conflicts that can impact on the literature, was shown in both Chapters One and Two. For example, Chapter Two, Section 2.3.1.2, looked at how editors can face conflicts with the owners of their publications over journal content. This has resulted in several instances, at high profile journals, of editors being fired. Despite this, there was, in practice, limited discussion of such conflicts in the data, or evidence of mechanisms to ensure editors are protected in this regard. Editors can also experience conflicts from a range of interests, which could affect

their publishing decisions, such as was the case with Alvan Feinstein, editor of *Circulation*, who was the recipient of tobacco industry funds, and published letters criticising research on deaths caused by second-hand tobacco smoke. Another obvious actor group that is absent from the debate over who can be conflicted are medical writers. Given the controversy that has surrounded the use of undisclosed medical writers in producing medical publications (see Chapter Two, Section 2.4), it might have been expected that their potential conflicts would be discussed in more detail within COI policies and guidance, and by interviewees. However, the focus is on authors, and the limited attention currently given to other groups of actors, means that any COIs they have may escape sufficient and effective management.

Similarly, the focus in both the literature and the data is primarily on financial interests, while other, non-financial ones receive limited attention. Again, this means that non-financial interests, which could have an impact on journal publications, often remain unmanaged. This is despite the fact that, as the literature explored in Chapter Two showed, individuals are not only driven by economic concerns (e.g. Woll, 2008), and thus non-financial interests can also present conflicts. For example, as argued by Gieryn (1983), the process of science is intrinsically linked to other intellectual activities, such as professional or political ideologies, and will therefore be influenced by them. However, as the literature and data demonstrated, the emphasis is placed on financial interests, and this was therefore reflected in the research findings. In particular, the literature and data focuses on the influence of private companies, such as those from the pharmaceutical and tobacco industries, on research and publications; this thesis has therefore similarly looked in more depth at the conflicts that emerge from such relationships, despite the fact that third-sector and government funding can also result in them (Smith, 2010, Dreger, 2015).

The principal reliance and focus on voluntary disclosure as a process to deal with conflicts, as discussed in Chapters Six and Eight, also means that alternative methods, which could improve the regulation of COIs, are not

considered. Voluntary disclosure is a useful tool, but is not on its own sufficient. As shown in Chapter Two, Section 2.5.1, the process has various inherent limitations. Most fundamentally, it is reliant on the honesty of those who are disclosing. It also depends on them having an awareness of what might have caused them to be biased (Cain and Detsky, 2008, Dana and Loewenstein, 2003, Pronin et al., 2004). There are also risks that disclosure may lead to the strengthening of conflicts (Cain et al., 2005b, Kassirer, 2009a). As such, relying solely on this system is problematic, as this thesis demonstrates is the case in medical journal publishing. Chapter Eight explored how the effective management of COIs would benefit from either further supporting mechanisms, or perhaps more fundamental changes.

Chapter Seven presented six additional such processes, which could work alongside disclosure to regulate the influence of COIs in the existing system of medical/health research and publishing. These were: clinical trial registration, clinical trial protocols, reporting guidelines, journal oversight committees, peer review and non-publication policies. If utilised sufficiently, these could perhaps help COIs to be managed more effectively. Building on the concept of disclosure, and representing an incremental change to the system, the idea of a central repository to store COI information was also raised; while this would not necessarily avoid some of the more fundamental problems associated with disclosure as discussed above, it would help to streamline the process and make it easier for actors to manage. More radical changes to the processes of publishing and funding, as mooted by several interviewees, were also examined. All of these ideas suggest that the possibility for change and improvement in the management of COIs within medical journal publishing exists; however, as Chapter Eight suggested, for these to be considered, actors within the institutional environment of medical journal publishing need to critically examine existing understandings surrounding COIs and be open and responsive to the possibility of new, alternative ideas.



### **9.3 Contributions to the literature**

Drawing on two sources of data – guidelines and policies developed by a range of organisational actors, and 48 original interviews with individual actors working in a variety of job roles from across the institutional environment of medical journal publishing – this study offers an original, empirical insight into medical journal publishing and the topic of COIs within it. The research demonstrates that, despite existing evidence of how a range of actor groups can have COIs that could potentially impact on the medical/health journal literature, the focus of key organisational and individual actors remains on the COIs of authors (Chapter Five). Thus, the COIs of other actor groups may continue to have an affect the content of journals. This research has also shown that attention is given to financial COIs, with limited discussion of other, non-financial types (for example, employment, political ideologies, family relationships): because these types of interest are less tangible, they appear to be largely ignored. This is despite the fact that, as shown in Chapter Two and the results chapters, they can also be problematic and therefore do require effective management; more research could usefully be done into this area (see Chapter Eight, Section 8.5). Finally, this study shows that disclosure remains the key method of regulating COIs. This is despite the fact that, while a useful tool, it has clear weaknesses and is thus not on its own a sufficient mechanism (Chapter Six). It has also shown that, due to an institutionalised way of thinking, the majority of actors currently have difficulty in considering how to change these existing conceptualisations. Yet some alternatives, both existing and potential, incremental and more fundamental, were proposed by several key actors when questioned directly on this. This research is the first to collate and examine such ideas. These perhaps offer the possibility of improved regulation of COIs, and are thus worthy of taking forward for further investigation.

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## Appendix I: Journals' policies and guidelines on COI that were included in the analysis

Journal	Guidance (URLs last accessed 2 <sup>nd</sup> December 2016)	Target Audience	Format
<i>NEJM</i>	Author center ( <a href="http://www.nejm.org/page/author-center/home">http://www.nejm.org/page/author-center/home</a> )	Authors	Webpage
	ICMJE disclosure form (ICMJE, n.d.)	Authors	Pdf document
	NEJM submission process	Authors	Online submission form
	Media center: integrity safeguards ( <a href="http://www.nejm.org/page/media-center/integrity-safeguards">http://www.nejm.org/page/media-center/integrity-safeguards</a> )	All	Webpage
	Editorial policies (New England Journal of Medicine, 2016)	All	Webpage
<i>The Lancet</i>	ICMJE disclosure form (ICMJE, n.d.)	Authors	Pdf document
	Author statements	Authors	Pdf form
	Information for authors	Authors	Pdf document
	<i>The Lancet's</i> policy on conflicts of interest (James and Horton, 2003, James et al., 2004)	All	Article
	<i>The Lancet</i> Submission Process	Authors	Online submission form

<i>JAMA</i>	JAMA 'Authorship responsibility, conflicts of interest and funding, and copyright transfer/publishing agreement'	Authors	Pdf form
	ICMJE disclosure form (ICMJE, n.d.)	Authors	Pdf document
	Editorial policies for authors (Journal of the American Medical Association, 2016)	Authors	Webpage
	JAMA submission process	Authors	Online submission form
<i>BMJ</i>	Authorship & contributorship (British Medical Journal, 2016a)	Authors	Webpage
	Forms, policies, and checklists ( <a href="http://www.bmj.com/about-bmj/resources-authors/forms-policies-and-checklists">http://www.bmj.com/about-bmj/resources-authors/forms-policies-and-checklists</a> )	Authors	Webpage
	ICMJE disclosure form (ICMJE, n.d.)	Authors	Pdf document
	BMJ submission process	Authors	Online submission form
	Transparency policy (British Medical Journal, 2016f)	Authors	Webpage
	BMJ Group policy on declaration of interests (BMJ Group, 2012b)	Editors, Authors, Reviewers	Online pdf document

<i>PLoS Medicine</i>	Editorial and publishing policies (PLoS, n.d.)	Editors, Authors, Reviewers	Webpage
	Reviewer guidelines (PLoS Medicine, n.d.-d)	Reviewers	Webpage
	PLoS policy on declaration and evaluation of competing interests (PLoS Medicine, n.d.-b)	Authors, Editors, Readers	Webpage
	PLoS authorship guidelines (PLoS Medicine, n.d.-a)	Authors	Webpage
	PLoS submission process	Authors	Online submission form
<i>Annals</i>	'ACP Conflict of interest: policies and procedures '(American College of Physicians, 2009)	Editors	Webpage
	Information for authors (Annals of Internal Medicine, 2014)	Authors	Webpage
	Annals submission process	Authors	Online submission form
<i>BMC Medicine</i>	Editorial policy: competing interests (BMC Medicine, 2016a)	Authors	Webpage
	Submission guidelines (BMC Medicine, 2016b)	Authors	Webpage

	Guide for <i>BMC Medicine</i> Reviewers (BMC Medicine, 2014a)	Reviewers	Webpage
<i>MAJ</i>	'Competing interests of authors: We have revised our policy' (Stanbrook et al., 2009)	Authors, Editors, Readers	Editorial
	ICMJE disclosure form (ICMJE, n.d.)	Authors	Pdf form
	Submission guidelines (CMAJ, 2016)	Authors	Webpage
	Submission process	Authors	Online submission form
<i>JIM</i>	Conflict of interest form	Authors	Word document
	Author guidelines (Journal of Internal Medicine - Author Guidelines - Wiley Online Library)	Authors	Webpage
	Submission process	Authors	Word document
<i>Mayo Clinic Proceedings</i>	Instructions to reviewers ( <a href="http://www.mayoclinicproceedings.org/pb/assets/raw/Health%20Advance/journals/jmcp/Reviewer.pdf">http://www.mayoclinicproceedings.org/pb/assets/raw/Health%20Advance/journals/jmcp/Reviewer.pdf</a> )	Reviewers	Online pdf document
	Author responsibility, financial disclosure, copyright Transfer, and acknowledgment	Authors	Online pdf form

	Submission process	Authors	Online submission form
	Instructions for authors ( <a href="https://www.elsevier.com/journals/mayo-clinic-proceedings/0025-6196/guide-for-authors">https://www.elsevier.com/journals/mayo-clinic-proceedings/0025-6196/guide-for-authors</a> )	Authors	Webpage
<i>AJC</i>	'Info for authors' (The American Journal of Cardiology, 2016)	Authors	Webpage
<i>AJM</i>	Conflict of interest statement <a href="http://www.elsevier.com/_data/promis_misc/ajmcoi.doc">http://www.elsevier.com/_data/promis_misc/ajmcoi.doc</a> )	Authors, Editors, Reviewers	Word Document
	AJM Submission process	Authors	Online submission form
	Guide to authors	Authors	Webpage
<i>AJOG</i>	Information for authors	Authors	Webpage
	Conflict of interest statement ( <a href="https://www.elsevier.com/_data/promis_misc/ajogcoi.pdf">https://www.elsevier.com/_data/promis_misc/ajogcoi.pdf</a> )	Authors, Editors, Reviewers	Pdf document
	Specific inappropriate acts in the publication process	Authors, Editors	Pdf document
	AJOG Submission process	Authors	Online submission form



	Submission checklist ( <a href="http://www.ajog.org/pb/assets/raw/Health%20Advance/journals/ymob/ajogchecklist2012.pdf">http://www.ajog.org/pb/assets/raw/Health%20Advance/journals/ymob/ajogchecklist2012.pdf</a> )	Authors	Pdf form
<i>Birth Defects</i>	Birth Defects submission process	Authors	Online submission form
<i>Clinical Therapeutics</i>	Author information pack (Clinical Therapeutics, 2016)	Authors	
<i>Environmental Technology</i>	Environmental Technology submission process	Authors	Online submission form
<i>IAOEH</i>	Instructions for authors ( <a href="http://www.springer.com/environment/environmental+health+-+public+health/journal/420">http://www.springer.com/environment/environmental+health+-+public+health/journal/420</a> )	Authors	Webpage
<i>JAACAP</i>	Quick guide for JAACAP reviewers ( <a href="http://www.jaacap.com/pb/assets/raw/Health%20Advance/journals/jaac/reviewers.pdf">http://www.jaacap.com/pb/assets/raw/Health%20Advance/journals/jaac/reviewers.pdf</a> )	Reviewers	Online pdf document
	JAACAP Manuscript submission form	Authors	Pdf form
	JAACAP Guide for authors ( <a href="https://www.elsevier.com/_data/promis_misc/JAAC_GFA-8-9-16.pdf">https://www.elsevier.com/_data/promis_misc/JAAC_GFA-8-9-16.pdf</a> )	Authors	Online pdf document

<i>JCP</i>	Authorship statement, copyright transfer, financial disclosure, and acknowledgment permission	Authors	Pdf form
	Information for authors ( <a href="http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1097-4679/homepage/ForAuthors.html">http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1097-4679/homepage/ForAuthors.html</a> )	Authors	Webpage
	Information for reviewers ( <a href="https://authorservices.wiley.com/Reviewers/journal-reviewers/index.html">https://authorservices.wiley.com/Reviewers/journal-reviewers/index.html</a> )	Reviewers	Webpage
	JCP submission process	Authors	Online submission form
<i>JNCI</i>	Author instructions ( <a href="http://www.oxfordjournals.org/our_journals/jnci/for_authors/author_forms.html">http://www.oxfordjournals.org/our_journals/jnci/for_authors/author_forms.html</a> )	Authors	Webpage
	JNCI submission process	Authors	Online submission form
<i>Risk Analysis</i>	Risk Analysis submission process	Authors	Online submission form



## Appendix II: Sample Interview Schedule

### *Introduction*

Thank you for taking the time to be interviewed. I'm carrying out research on publishing ethics in medical journals, and am interested in investigating the methods used to deal with conflicts of interest, in particular those policies created by journals and trade organisations. I'm therefore interested in speaking to you due to your work in medical journal publishing.

As stated on the participant information sheet, this interview is confidential and your name will not appear in anything I write, unless you would like it to. If you agree, I will be recording this interview.

### *Contextual*

### *Information*

- 1) First I would like to ask a few questions about you and your work:
  - a) What is your involvement with medical journal publishing?
  - b) Why did you participate in this conference and how did it relate to your work?
  - c) Have you been to any previous conference, or any others like it?

### *Medical Journal Publishing: Understanding of Issues*

2) There's been a lot of discussion about the ways in which academic medical journal articles can be misused. I would like to ask some general questions about these issues:

- a) What do you consider to currently be the main issues of ethical concern in academic medical journal publishing, and why do you think they are problematic?
- b) What is your understanding of the history of these issues – i.e. when and why did they emerge?
- c) How did you personally become aware of these issues?

- d) How much training have you and your colleagues received on these issues?
- e) Where does this training come from?

### *Conflicts of Interest*

3) I would now like to focus the discussion on the topic of conflicts of interest in medical publishing:

- a) What is your general understanding of conflicts of interest in relation to medical publishing?
- b) Who do you think might have conflicts of interest that could have an impact on the content of medical journals?
- c) Do you think conflicts of interest in medical publishing are problematic?
  - i. If so, what sorts of conflicts of interest do you think are of concern?
- d) Why do you think these conflicts arise?

### *Funding by Commercial Companies*

4) The funding of research by commercial companies potentially increases conflicts of interest and therefore the potential for bias in research and resulting articles. I'd like to ask a couple of questions about your thoughts on this.

- a) Do you think that, on the whole, research funded by commercial companies is more likely to include biases and lead to conflicts of interest than research funded from public sources?
- b) Do you think the funding of medical research by commercial companies is problematic? Why?
- c) Some journals now refuse to publish research funded by certain industries. What are your thoughts on that?

### *Regulating Conflicts of Interest*

- a) What guidance do you provide authors [and editors] on conflicts of interest?
- b) Do you ask authors to sign and return to you a conflict of interest statement? If so, what statement do you use?

- c) With whom do you think the responsibility in managing conflicts of interest primarily lies?  
- publishers, journal editors, commercial companies, authors, others, or a combination?
- d) What do you understand to currently be the main mechanisms to manage conflicts of interest in medical publishing?
  - a) How effective to you think these mechanisms are? Do you think it's possible for academic and publishing processes to identify biases arising from conflicts of interest? (If so, how? If not, why not?)
  - e) Do you think these mechanisms have changed over the last ten years? If so, how? If not, do you think they ought to have changed?
  - f) Overall, do you feel the current model of medical publishing enables conflicts of interest to potentially remain hidden?
    - i. If so, how?

#### *Current Publishing Policies and Guidelines*

5) I'd like to focus on the role of publishing policies and guidelines in managing the issues we've discussed, such as conflicts of interest – both those developed by individual journals and by trade organisations (e.g. ICMJE):

- a) How important a role do you consider publishing guidelines to be in managing these issues?
  - i. If limited, what purpose do you think they serve?
- b) How effective do you think these guidelines are in managing conflicts of interest?
- c) There are various guidelines developed by trade organisations. Which do you feel are the best known/utilised?
- d) How aware of the guidelines (both journals' and trade organisations') do you think are:
  - i. Authors
  - ii. Editors
  - iii. Commercial funders
- e) How easy do you think these guidelines are to follow?

- f) Do you expect authors to rely more on your journal's own guidelines, or on the guidance produced by other organisations?
- g) Was any other guidance used, or advice taken, in developing your journal's guidelines? If so, what?
- h) How do you ensure that authors have read and understood your journal's guidelines and any other relevant ones?
- i) What are the repercussions for authors or reviewers who you find have not abided by the guidelines?
- j) Do you feel current guidelines and policies on conflicts of interest are effective and sufficient in dealing with the problems, or could they be made more robust?
  - i. If so, how?
  - ii. What would need to happen to bring this about and when do you foresee this happening?

## Appendix III: Examples of sources of personal financial conflicts of interest given in sample journals' guidance

Journal	Examples of sources of financial conflicts of interest
<i>AJC</i>	'Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding'
<i>AJM</i>	'e.g. consultancies, employment, expert testimony, honoraria, retainers, stock) that may affect the conduct or reporting of the work submitted.'
<i>AJOG</i>	'Such conflicts, either direct or indirect, include any financial interest by the authors in a company producing products described in the submitted manuscript as well as stock, stock options, direct employment, consulting status, or membership in a speakers bureau.'
<i>Annals</i>	'Academic, financial, institutional, and personal relationships (such as employment, consultancies, close colleague or family ties, honoraria for advice or public speaking, service on advisory boards or medical education companies, stock ownership or options, paid expert testimony, grants or patents received or pending, and royalties)' ... 'These include, but are not limited to, any financial relationship that involves conditions or tests or treatments discussed in the manuscript and alternatives to the tests or treatments for those conditions.'



<i>Birth Defects Research Part B</i>	<p>'Potential sources of conflict of interest include but are not limited to patent or stock ownership, membership of a company board of directors, membership of a company board of directors, membership of an advisory board or committee for a company, and consultancy for or receipt of speaker's fees from a company.'</p>
<i>BMC Medicine</i>	<p>'Financial competing interests include (but are not limited to):</p> <p>Receiving reimbursements, fees, funding, or salary from an organization that may in any way gain or lose financially from the publication of the article, either now or in the future.</p> <p>Holding stocks or shares in an organization that may in any way gain or lose financially from the publication of the article, either now or in the future.</p> <p>Holding, or currently applying for, patents relating to the content of the manuscript.</p> <p>Receiving reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript.'</p>
<i>BMJ</i>	<p>'Personal financial interests</p> <p>A personal financial interest exists when payments are made directly to an individual, whether as a salary or as fees or honoraria; or where an individual receives benefits from a third party who is not their main employer, such as a fellowship, equipment, writing or administrative assistance, or travel and accommodation expenses; or where an individual owns stocks and shares, patents, or other assets.</p> <p>Examples include:</p>

	<p>Employment, Paid consultancy or directorship, Ownership of stocks and shares, Patent ownership or applications, Paid membership of speakers panels/bureaus and advisory board, Acting as an expert witness. Being in receipt of a fellowship, equipment, writing or administrative support, Travel and accommodation expenses. Writing or consulting for a medical education promotional or communications company</p> <p>No personal financial interest exists in the case of assets over which individuals have no control, for example, unit trusts, occupational pension funds, and accrued pension rights.'</p>
<i>Clinical Therapeutics</i>	<p>'Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. Authors should declare the role of study sponsors, if any, in the study design, in the collection, analysis and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. If the study sponsors had no such involvement, the authors should so state.'</p>
<i>CMAJ</i>	<p>'Financial relationships (such as employment, consultancies, stock ownership, honoraria, paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself.'</p>
<i>Environmental Technology</i>	<p>'A list of potential conflicts of interest in relation to the submitted manuscript could include:</p>

	<ul style="list-style-type: none"> <li>• Consultancies</li> <li>• Employment</li> <li>• Grants</li> <li>• Fees &amp; Honoraria</li> <li>• Patents</li> <li>• Royalties</li> <li>• Stock or share ownership</li> </ul> <p>If necessary, please describe any potential conflicts of interest in a covering letter, indicating funding when greater than US\$2000.00 per year.'</p>
<i>IAOEH</i>	'All benefits in any form from a commercial party related directly or indirectly to the subject of this manuscript or any of the authors must be acknowledged. For each source of funds, both the research funder and the grant number should be given. '
<i>JAACAP</i>	'This disclosure includes, but is not limited to, grants or funding, employment, affiliations, patents (in preparation, filed, or granted), inventions, honoraria, consultancies, royalties, stock options/ ownership, or expert testimony.'
<i>JAMA</i>	'Authors are expected to provide detailed information about all relevant financial interests, activities, relationships, and affiliations ... including, but not limited to, employment, affiliation, funding and grants received or pending, consultancies, honoraria or payment, speakers' bureaus, stock ownership or options, expert testimony, royalties, donation of medical equipment, or patents planned, pending, or issued.'

<i>JNCI</i>	<p>'Authors will be asked to disclose: 1) any financial interest in or arrangement with a company whose product was used in a study or is referred to in a Review, opinion piece, or letter, 2) any financial interest in or arrangement with a competing company, and 3) any other financial connections, direct or indirect, or other situations that might raise the question of bias in the work reported or the conclusions, implications, or opinions stated—including pertinent commercial or other sources of funding for the individual author(s) or for the associated department(s) or organization(s).'</p>
<i>JCP</i>	<p>'Personal financial interests, including stocks and shares in companies that may gain or lose financially from publication, consultation fees or forms of remuneration from organizations that may gain or lose financially, or patent and patent applications whose value may be affected ... Employment, whether recent, present or anticipated, by an organization that may gain or lose from publication of the paper.'</p>
<i>JIM</i>	<p>'Personal financial interests: Stocks or shares in companies that may gain or lose financially through publication; consultant fees or fees from speakers bureaus other forms of remuneration from organisations that may gain or lose financially; patents or patent applications whose value may be affected by publication.</p> <p>Employment: Recent, present or anticipated employment of you or a family member by any organization that may gain or lose financially through publication of the paper. Any such competing interest that authors may have should be declared. The aim of the statement is not to eradicate</p>

	<p>competing interests, as they are almost inevitable. Papers will not be rejected because there is a competing interest, but a declaration on whether or not there are competing interests will be added to the paper.</p> <ul style="list-style-type: none"> <li>-Patent rights</li> <li>-Consultancy work'</li> </ul>
<i>The Lancet</i>	<p>'A conflict of interest exists when professional judgement concerning a primary interest (such as patients' welfare or validity of research) may be influenced by a secondary interest (such as financial gain).'</p>
<i>Mayo</i>	<p>'Financial Disclosure. Any author who has a financial involvement with any organization or entity with a financial interest in or in financial competition with the subject matter or materials discussed in the manuscript should disclose that affiliation. Examples of financial involvement include employment, stock holdings (\$10,000 or 5% equity interest in a company), consultancies, financial support of research through grants or contracts, participation in a speaker's bureau, provision of expert testimony, or receipt of honoraria.'</p>
<i>NEJM</i>	<p>'Authors of research articles should disclose at the time of revision any financial arrangement they may have with a company whose product is pertinent to the submitted manuscript or with a company making a competing product.'</p>
<i>PLoS</i>	<p>'Financial competing interests include but are not limited to:</p> <ul style="list-style-type: none"> <li>- Ownership of stocks or shares</li> <li>- Paid employment or consultancy</li> </ul>

	<ul style="list-style-type: none"> <li>- Board membership</li> <li>- Patent applications (pending or actual), including individual applications or those belonging to the institution to which authors are affiliated and which the authors may benefit from</li> <li>- Research grants (from any source, restricted or unrestricted)</li> <li>- Travel grants and honoraria for speaking or participation at meetings</li> <li>- Gifts</li> </ul>
<i>Risk Analysis</i>	[On Submission COI form] Do you or any of your co-authors have an ownership stake, including publicly traded stock, in any company that may directly benefit from the publication of the article? (Ownership of diversified mutual funds does not need to be disclosed).



## Appendix IV: Guidance given on disclosure of funding in sample journals' guidance

Journal	Funding
<i>AJC</i>	'Examples of potential conflicts of interest include ... grants or other funding.'
<i>AJM</i>	None
<i>AJOG</i>	'You are requested to identify who provided financial support for the conduct of the research and/or preparation of the article and to briefly describe the role of the sponsor(s), if any, in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication.'
<i>Annals</i>	'Academic, financial, institutional, and personal relationships (such as ... grants ...)'
<i>Birth Defects Research Part B</i>	None
<i>BMC Medicine</i>	'Receiving reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript.'
<i>BMJ</i>	'Organisational financial interests An organisational financial interest exists where the interest belongs at arm's length to the individual—for example, where payments are made to the individual's organisation rather than



	<p>to their own bank account.</p> <p>Examples include:</p> <p>Research grants Funds for staff or department.'</p>
<i>Clinical Therapeutics</i>	<p>'Examples of potential conflicts of interest include ... grants or other funding. Authors should declare the role of study sponsors, if any, in the study design, in the collection, analysis and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. If the study sponsors had no such involvement, the authors should so state.'</p>
<i>CMAJ</i>	<p>'Potential Conflicts of Interest Related to Project Support</p> <p>Increasingly, individual studies receive funding from commercial firms, private foundations, and government. The conditions of this funding have the potential to bias and otherwise discredit the research.</p> <p>Scientists have an ethical obligation to submit creditable research results for publication. Moreover, as the persons directly responsible for their work, researchers should not enter into agreements that interfere with their access to the data and their ability to analyze it independently, to prepare manuscripts, and to publish them. Authors should describe the role of the study sponsor(s), if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the report for publication. If the supporting source had no such involvement, the authors should so state. Biases potentially introduced when sponsors are directly involved in research are analogous to methodological biases of other sorts. Some journals, therefore,</p>

	<p>choose to include information about the sponsor's involvement in the methods section.</p> <p>Editors may request that authors of a study funded by an agency with a proprietary or financial interest in the outcome sign a statement such as, "I had full access to all of the data in this study and I take complete responsibility for the integrity of the data and the accuracy of the data analysis." Editors should be encouraged to review copies of the protocol and/or contracts associated with project-specific studies before accepting such studies for publication. Editors may choose not to consider an article if a sponsor has asserted control over the authors' right to publish.'</p>
<i>Environmental Technology</i>	<p>'Authors should also include a relevant Disclosure Statement along with the text of their article, in conjunction with any Acknowledgements and Details of Funders.'</p> <p>'All funding sources supporting the work should also be acknowledged.'</p> <p>The name of any/all third-party funders must be given in full. In addition, the <b>full names</b> and <b>numbers</b> of all grants must be given in the acknowledgments section of your article.'</p>
<i>IAOEH</i>	<p>All benefits in any form from a commercial party related directly or indirectly to the subject of this manuscript or any of the authors must be acknowledged. For each source of funds, both the research funder and the grant number should be given.</p>
<i>JAACAP</i>	<p>'This disclosure includes, but is not limited to, grants or funding.'</p>

<i>JAMA</i>	<p>‘Authors are expected to provide detailed information about all relevant financial interests, activities, relationships, and affiliations ... including, but not limited to ... funding and grants received or pending’</p> <p>...</p> <p>Authors also are required to report detailed information regarding all financial and material support for the research and work, including but not limited to grant support, funding sources, and provision of equipment and supplies, in the Acknowledgment section of the manuscript.’</p>
<i>JCP</i>	<p>‘Authors are required to provide a statement covering any conflict of interest that may arise from publication of their manuscript. This includes, but is not limited to:</p> <p>Funding, including salaries, equipment, supplies, reimbursement for attending symposia, etc, from organizations that may gain or lose financially through the publication of the paper’</p>
<i>JIM</i>	<p>‘Funding: Research support from organisations that might gain or lose financially through publication of the paper.’</p> <p>‘All sources of funding must be disclosed in the Acknowledgments section of the paper. List governmental, industrial, charitable, philanthropic and/or personal sources of funding used for the studies described in the manuscript. Attribution of these funding sources is preferred.’</p>
<i>JNCI</i>	<p>‘Authors will be asked to disclose ... any other financial connections, direct or indirect, or other situations that might</p>

	raise the question of bias in the work reported or the conclusions, implications, or opinions stated—including pertinent commercial or other sources of funding for the individual author(s) or for the associated department(s) or organization(s).'
<i>The Lancet</i>	<p>'All sources of funding should be declared as an acknowledgment at the end of the text</p> <p>At the end of the Methods section, under a subheading "Role of the funding source", authors must describe the role of the study sponsor(s), if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication</p> <p>If there is no Methods section, the role of the funding source should be stated as an acknowledgment. If the funding source had no such involvement, the authors should so state</p> <p>The corresponding author should confirm that he or she had full access to all the data in the study and had final responsibility for the decision to submit for publication'</p>
<i>Mayo</i>	'The manuscript should also clearly identify the financial support of the research described in the currently submitted manuscript.'
<i>NEJM</i>	<p>'Authors of research articles should disclose at the time of revision any financial arrangement they may have with a company whose product is pertinent to the submitted manuscript or with a company making a competing product.'</p> <p>'For all research articles we publish, NEJM lists study sponsorship and relevant financial information as disclosed by</p>

	the authors.'
<i>PLoS</i>	<p>'Financial competing interests include but are not limited to ... Research grants (from any source, restricted or unrestricted)'</p> <p>'In addition, we require that the role of all funding sources in the work be described, and authors are required to state explicitly whether the funder was involved in the study design; collection, analysis and interpretation of data; writing of the paper; and/or decision to submit for publication.'</p>
<i>Risk Analysis</i>	[Submission COI form]: 'Did you or your co-author(s) receive any external financial support for the work presented in this manuscript?'

## Appendix V: Journals' guidance on editors' COIs

Journal	Financial	Non-Financial
<i>NEJM</i>	'NEJM's policy is that none of the NEJM editors should have any financial relationship with any biomedical company'.	None
<i>The Lancet</i>	None	None
<i>JAMA</i>	None	None
<i>BMJ</i>	None	None
<i>PLoS Medicine</i>	'academic and professional editors, paid or unpaid, must consider and declare any potential financial relationships that could reasonably be perceived as relevant and/or could influence their objective review of the paper.'	<p>'editors... must consider and then disclose whether they have any potential non-financial interests that might influence their reporting, handling, or review of the paper, or that might be negatively or positively affected by publication of the paper.'</p> <p>'editors – academic or professional, paid or unpaid – are required to recuse themselves from deliberations if they cannot evaluate a paper in an objective way because of personal relationships with authors.'</p>
<i>Annals</i>	'editors ... must state explicitly whether potential conflicts do or do not exist. Academic, financial,	'Editors recuse themselves from discussing manuscripts and avoid participation in decisions about manuscripts if they have a close

	<p>institutional, and personal relationships (such as employment, consultancies, close colleague or family ties, honoraria for advice or public speaking, service on advisory boards or medical education companies, stock ownership or options, paid expert testimony, grants or patents received or pending, and royalties) are potential conflicts of interest that could undermine the credibility of the journal, the authors, and science itself. ... editors must disclose ... all financial relationships that could be viewed as presenting a potential conflict of interest. These include, but are not limited to, any financial relationship that involves conditions or tests or treatments discussed in the manuscript and alternatives to the tests or treatments for those conditions. If persons are uncertain, they should err on the side of full</p>	<p>personal or professional relationship with any of the authors.'</p> <p>'editors ... must state explicitly whether potential conflicts do or do not exist. Academic, financial, institutional, and personal relationships (such as employment, consultancies, close colleague or family ties, honoraria for advice or public speaking, service on advisory boards or medical education companies, stock ownership or options, paid expert testimony, grants or patents received or pending, and royalties) are potential conflicts of interest that could undermine the credibility of the journal, the authors, and science itself. ... editors must disclose their primary academic and institutional affiliations ... that could be viewed as presenting a potential conflict of interest.</p>
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	disclosure.	
<i>BMC Medicine</i>	'Editors ... are also required to declare any competing interests and will be excluded from the peer review process if a competing interest exists.'	'Editors ... are also required to declare any competing interests and will be excluded from the peer review process if a competing interest exists.'
<i>CMAJ</i>	'Editors who make final decisions about manuscripts must have no ... financial involvement in any of the issues they might judge. Other members of the editorial staff, if they participate in editorial decisions, must provide editors with a current description of their financial interests (as they might relate to editorial judgments) and disqualify themselves from any decisions where they have a conflict of interest. Editorial staff must not use the information gained through working with manuscripts for private gain.'	'Editors who make final decisions about manuscripts must have no personal, professional ... involvement in any of the issues they might judge. Other members of the editorial staff, if they participate in editorial decisions, must ... disqualify themselves from any decisions where they have a conflict of interest. Editorial staff must not use the information gained through working with manuscripts for private gain.'
<i>JIM</i>	'Journal editors, Editorial Board members and other editorial staff (including	'Editors or Editorial Board members are never involved in editorial decisions about their



	peer reviewers) withdraw from discussions about submissions where any circumstances might prevent him/her offering unbiased editorial decisions. ‘	own work. ... When making editorial decisions about peer reviewed articles where an editor is an author or is acknowledged as a contributor, affected editors or staff members exclude themselves and are not involved in the publication decision. When editors are presented with papers where their own interests may impair their ability to make an unbiased editorial decision, he/she deputises decisions about the paper to a suitably qualified individual.’
<i>Mayo Clinic Proceedings</i>	None	None
<i>AJC</i>	None	None
<i>AJM</i>	‘The editor should not handle a manuscript if there is a potential conflict of interest. This includes financial interest.’	‘The editor should not handle a manuscript if there is a potential conflict of interest. This includes ... positive or negative biases toward the author or companies producing materials described in the article.
<i>AJOG</i>	‘The editor should not handle a manuscript if there is a potential conflict of interest. This includes financial interests.’	‘The editor should not handle a manuscript if there is a potential conflict of interest. This includes ... positive or negative biases toward the authors or companies

		producing materials described in the article.'
<i>Birth Defects</i>	None	None
<i>Clinical Therapeutics</i>	None	None
<i>Environmental Technology</i>	None	None
<i>IAOEH</i>	None	None
<i>JAACAP</i>	None	None
<i>JCP</i>	None	None
<i>JNCI</i>	None	None
<i>Risk Analysis</i>	None	None



## Appendix VI: Journals' guidance on reviewers' COIs

Journal	Financial	Non-Financial
<i>NEJM</i>	None	None
<i>The Lancet</i>	None	None
<i>JAMA</i>	None	None
<i>BMJ</i>	<p>'We used to ask authors and reviewers about any competing interests, but we have decided to restrict our request to financial interests. Please answer the following questions</p> <p>Have you in the past five years accepted the following from an organisation that may in any way gain or lose financially from the publication of this paper:</p> <ul style="list-style-type: none"> <li>- Reimbursement for attending a symposium?</li> <li>- A fee for speaking?</li> <li>- A fee for organising education?</li> <li>- Funds for research?</li> <li>- Funds for a member of staff?</li> <li>- Fees for consulting?</li> <li>- Have you in the past five years been employed by an organisation that may in any way gain or lose financially</li> </ul>	<p>'We are restricting ourselves to asking directly about competing financial interests, but you might want to disclose another sort of competing interest that would embarrass you if it became generally known after publication. The following list gives some examples.</p> <ul style="list-style-type: none"> <li>- A close relationship with, or a strong antipathy to, a person whose interests may be affected by publication of your paper.</li> <li>- An academic link or rivalry with somebody whose interests may be affected by publication of your paper.</li> <li>- Membership of a political party or special interest group whose interests may be affected by publication of your paper.</li> <li>- A deep personal or religious</li> </ul>

	<p>from the publication of this paper?</p> <p>- Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this paper?</p> <p>- Have you acted as an expert witness on the subject of your study, review, editorial, or letter?</p> <p>- Do you have any other competing financial interests? If so, please specify.'</p>	<p>conviction that may have affected what you wrote and that readers should be aware of when reading your paper.'</p>
<i>PLoS Medicine</i>	<p>'reviewers ... paid or unpaid, must consider and declare any potential financial relationships that could reasonably be perceived as relevant and/or could influence their objective review of the paper'</p> <p>'Reviewers are required to declare if they have held grants ... with the authors of the study they are asked to review.'</p>	<p>'reviewers ... must consider and then disclose whether they have any potential non-financial interests that might influence their reporting, handling, or review of the paper, or that might be negatively or positively affected by publication of the paper.'</p> <p>'Reviewers are required to declare if they have ... co-authored papers, or worked in the same institution or organization with the authors of the study they are asked to</p>

		review, or if they are in an adversarial relationship with authors.'
<i>Annals</i>	<p>'peer reviewers must disclose ... all financial relationships that could be viewed as presenting a potential conflict of interest.'</p> <p>'peer reviewers must state explicitly whether potential conflicts do or do not exist. ... financial... relationships (such as employment, consultancies ... honoraria for advice or public speaking, service on advisory boards or medical education companies, stock ownership or options, paid expert testimony, grants or patents received or pending, and royalties) are potential conflicts of interest that could undermine the credibility of the journal, the authors, and science itself.</p> <p>... peer reviewers must disclose ... all financial relationships that could be viewed as presenting a potential conflict of interest.</p>	<p>'peer reviewers must disclose their primary academic and institutional affiliations.'</p> <p>'We ask reviewers to declare potential conflicts of interest and to decline the opportunity to review if they think that a close personal or professional relationship with any of the authors could lead to a review that would be different than if no such relationship existed.'</p> <p>'peer reviewers must state explicitly whether potential conflicts do or do not exist. Academic ... institutional, and personal relationships (such as ... close colleague or family ties ...) are potential conflicts of interest that could undermine the credibility of the journal, the authors, and science itself.</p> <p>... peer reviewers must disclose their primary academic and institutional affiliations ....</p>

	These include, but are not limited to, any financial relationship that involves conditions or tests or treatments discussed in the manuscript and alternatives to the tests or treatments for those conditions.	
<i>BMC Medicine</i>	'reviewers are also required to declare any competing interests and will be excluded from the peer review process if a competing interest exists.'	'reviewers are also required to declare any competing interests and will be excluded from the peer review process if a competing interest exists.'
<i>CMAJ</i>	'All participants in the peer review and publication process must disclose all relationships that could be viewed as presenting a potential conflict of interest. .... Editors should publish this information if they believe it is important in judging the manuscript.'	<p>'All participants in the peer review and publication process must disclose all relationships that could be viewed as presenting a potential conflict of interest. .... Editors should publish this information if they believe it is important in judging the manuscript.'</p> <p>'Editors should avoid selecting external peer reviewers with obvious potential conflicts of interest, for example, those who work in the same department or institution as any of the authors.'</p>

<i>JIM</i>	'We will also ask reviewers to provide a statement of competing interests'	'We will also ask reviewers to provide a statement of competing interests'
<i>Mayo Clinic Proceedings</i>	'Please consider any conflict of interest issues you may have with the topic, authors, or related affiliations that may hinder you from providing a fair and balanced review (if you are unsure, please contact the Editorial Office for clarification).'	'Please consider any conflict of interest issues you may have with the topic, authors, or related affiliations that may hinder you from providing a fair and balanced review (if you are unsure, please contact the Editorial Office for clarification).'
<i>AJC</i>	None	None
<i>AJM</i>	'Reviewers must disclose any financial interest they have in the companies producing pharmaceuticals, supplies or equipment to the medical profession. Such financial interest includes stock, direct employment, stock options, consultant or membership in a speaker's bureau.'	'Reviewers should not accept an assignment if they have prior or current close relationships (mentor or colleague) with the authors. Reviewers should not accept the assignment if there is a competitive relationship with or a negative bias toward the authors.'
<i>AJOG</i>	'Reviewers must disclose any financial interest they have in companies producing pharmaceuticals, supplies, or equipment to the medical profession. Such financial interest includes stock, direct employment, stock options,	'Reviewers should not accept an assignment if they have prior or current close relationships (mentor or colleague) with the authors. Reviewers should not accept the assignment if there is a competitive relationship with



	consultant, or membership in a speaker's bureau.'	or a negative bias toward the authors.'
<i>Birth Defects</i>	None	None
<i>Clinical Therapeutics</i>	None	None
<i>Environmental Technology</i>	None	None
<i>IAOEH</i>	'relationships, both financial and personal, that might prevent an unbiased and objective evaluation of the work'	'relationships, both financial and personal, that might prevent an unbiased and objective evaluation of the work'
<i>JAACAP</i>	None	None
<i>JCP</i>	'Reviewers who have a financial ... conflict of interest related to a manuscript are obligated to decline the reviewer position.'	'Reviewers who have a ... personal conflict of interest related to a manuscript are obligated to decline the reviewer position.'
<i>JNCI</i>	None	None
<i>Risk Analysis</i>	None	None

## Appendix VII: Extracts from journals' guidance on conflicts of interest in relation to article type

Journal <sup>25</sup>	Extract from journals' COI policies regarding the type of article
<i>NEJM</i> *	'Because the essence of reviews and editorials is selection and interpretation of the literature, the <i>Journal</i> expects that authors of such articles will not have any significant financial interest in a company (or its competitor) that makes a product discussed in the article'.
<i>The Lancet</i> *	'For Comment, Seminars, Reviews and Series, <i>The Lancet</i> will not publish if an author, within the past 3 years, and with a relevant company or competitor, has any stocks or shares, equity, a contract of employment, or a named position on a company board; or has been asked by any organisation other than <i>The Lancet</i> to write, be named on, or to submit the paper.'
<i>JAMA</i> *	'The policy requiring disclosure of conflicts of interest applies for all manuscript submissions, including letters to the editor.'
<i>BMJ</i> <sup>26*</sup>	' <i>For Research articles</i> All authors have completed the ICMJE uniform disclosure form ... <i>For Non-research articles</i> I/we have read and understood the BMJ Group policy on declaration of interests and declare the following interests.'
<i>PLoS Medicine</i> *	'With respect to commissioned or other non-research articles, PLoS editors do not commission or publish any such article,

25 High IF journals are marked with an asterisk.

26 As of 2015 the *BMJ* introduced a new policy whereby they would not publish editorials and clinical education articles from authors with financial ties to industry CHEW, M., BRIZZELL, C., ABBASI, K. & GODLEE, F. 2014. *Medical Journals and Industry Ties*..

	which comments or reviews research findings or other topics, if they are aware of a competing interest that in their judgment could introduce bias or the reasonable perception of bias.'
<i>Annals*</i>	'Disclosure of these relationships is essential not only for original research articles but also for editorials, letters, commentary, and review articles. ... Annals avoids publishing editorials, reviews, and guidelines authored by individuals with potential financial conflicts of interest, but considers each such manuscript on a case-by-case basis.'
<i>BMC Medicine*</i>	None
<i>CMAJ*</i>	None
<i>JIM*</i>	None
<i>Mayo Clinic Proceedings*</i>	None
<i>AJC</i>	None
<i>AJM</i>	'Authors of research articles should disclose any affiliation with any organization with a financial interest, direct or indirect, in the subject matter or materials discussed in the manuscript ... that may affect the conduct or reporting of the work submitted ... Because reviews and editorials are based on selection and interpretation of the literature, the Journal expects that authors of such articles will not have any financial interest in a company (or its competitor) that makes a product discussed in the article.'
<i>AJOG</i>	None
<i>Birth Defects</i>	None
<i>Clinical Therapeutics</i>	None
<i>Environmental Technology</i>	None
<i>IAOEH</i>	None

<i>JAACAP</i>	'JAACAP requires all authors on all types of articles (including letters) to specify the nature of all biomedical financial interests and potential conflicts of interest, financial or otherwise.'
<i>JCP</i>	None
<i>JNCI</i>	'Journal policy requires that all authors of research papers, Reviews, Commentaries, and Correspondences complete a Conflict of interest disclosure form ... Potential Editorialists will be required to complete a Conflict of Interest form at invitation ... Authors will be asked to disclose: any financial interest in or arrangement with a company whose product was used in a study or is referred to in a Review, opinion piece, or letter'.
<i>Risk Analysis</i>	None



## **Appendix VIII: Sample Participant Information Sheet**

**Department:** Global Public Health Unit, Social Policy

**Title of Study:** Communication Ethics in Medical Journal Publications

### **Introduction**

This research is being conducted by Rachel Hendrick, a doctoral student in the School of Social and Political Science at the University of Edinburgh ([R.Hendrick@sms.ed.ac.uk](mailto:R.Hendrick@sms.ed.ac.uk)). It is being supervised by Professor Jeff Collin and Dr Katherine Smith at the University of Edinburgh. It is funded by the Economic and Social Research Council (ESRC) with support from the British Medical Journal (BMJ).

### **What is the purpose of this investigation?**

Various areas of concern exist regarding the publication of medical journal articles. This project aims to investigate the ethical issues surrounding conflicts of interest in articles, and how the challenges they pose are currently being addressed through the development of various policies and guidelines that encourage disclosure by those involved in the production of articles.

The researcher is interested in the development of these policies and guidelines, and how those working in the medical publishing industry perceive their success in combating the concerns. Interviews are therefore being conducted with those working in the field (for example, publishers, journal editors, authors, publication planners and medical writers). It is envisaged that this study will contribute to the continuing debate and literature in the area, and will lead to practical recommendations on how to respond to the issues.

### **Why have you been invited to take part?**

You have been asked to participate in this study and provide your perspective because you are (or have been) involved in matters relating to the topic area, and as such are able to provide valuable insights.

**What will you do in the project?**

If you agree to be interviewed, a location and time for the interview will be agreed with you. You will be asked to provide approximately one hour of your time. During the interview, we will discuss matters relating to the topic under investigation. The format will be a semi-formal interview, in which you will be asked a range of questions regarding your area of work/expertise. The interview will be recorded, unless you request otherwise, in which case written notes will be taken.

At the end of the interview you will have the opportunity to raise any questions regarding the interview, the wider project, or any other related questions. You may be asked if you know of related individuals involved in similar work who may be able to speak to the researcher; however, you are under no obligation to provide such information.

**Do you have to take part?**

Participation in these interviews is entirely voluntary: you are not obliged to take part, and you may withdraw from the study if you wish at any point, without detriment. If you wish to withdraw, please just email the researcher or her supervisors (contact details below)

**What happens to the information in the project?**

The information that you provide in the interview will be used (quoted and referenced) by the researcher in their final PhD thesis, and in related academic ventures such as conference presentations, journal articles, and publications in the *British Medical Journal*.

If you choose to participate under conditions of anonymity, your identity will never be deliberately revealed.

Your personal details, audio data and interview transcripts will be securely stored on a password-protected computer with the potential for follow-up work.

Reflecting the ESRC's data archiving and data sharing policy, the consent form on the following page asks whether you would be willing for copies of the interview data to be provided to the UK Data Archive. This would enable the data to be used by others at a later date. If you have requested anonymity, this will be respected and only anonymised versions of the transcripts/interview notes will be archived (with no personal details relating to you). However, this is entirely optional and, if you prefer, the transcript/notes relating to your interview will not to be archived.

The University of Edinburgh is registered with the Information Commissioner's Office who implements the Data Protection Act 1998. All personal data on participants will be processed in accordance with the provisions of the Data Protection Act 1998.

**Thank you for reading this information – please ask any questions if you are unsure about what is written here.**

### **What happens next?**

If you are happy to participate in this study, please sign the consent form below, a copy of which you should retain for your own records. If you do not wish to participate, I would like to thank you for taking the time to consider the proposal.

This investigation has been granted ethical approval by the University of Edinburgh School of Social and Political Science's Ethics Committee.

If you have any questions or concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed, please contact: Professor Jeff Collin (Jeff.Collin@ed.ac.uk) or Dr Katherine Smith (Katherine.Smith@ed.ac.uk) who are supervising this research.



Researcher Contact Details:

Rachel Hendrick

Doctoral Student

School of Social and Political Science 15a George Square

Edinburgh EH8 9LD [R.Hendrick@sms.ed.ac.uk](mailto:R.Hendrick@sms.ed.ac.uk)

**Consent Form**

**Department:** Global Public Health Unit, Social Policy

**Title of Study:** Communication Ethics in Medical Journal Publications

I confirm that I have read and understood the information sheet for the above project and the researcher has answered any queries to my satisfaction.

I understand that my participation is voluntary and that I am free to withdraw from the project at any time, without having to give a reason and without any consequences, and that to do so I should contact Rachel Hendrick

[R.Hendrick@sms.ed.ac.uk](mailto:R.Hendrick@sms.ed.ac.uk)).

I understand that I can withdraw my data from the study at any time before the end of the project by contacting Rachel Hendrick ([R.Hendrick@sms.ed.ac.uk](mailto:R.Hendrick@sms.ed.ac.uk)).

I understand that I have the right to request that information recorded in the interview will not be attributed to me and that, if I request anonymity, no information that identifies me will be made publicly available.

I consent to being a participant in the project

I consent to being audio recorded as part of the project (please tick):

Yes	
No	

I would prefer information recorded in the interview to be (please tick):

Attributed to	
Anonymised	

I consent to having anonymised copies of the interview transcript/notes archived in the UK Data Archive (<http://data-archive.ac.uk/>) as part of the ESRC's efforts to promote data archiving and data sharing:

Yes	
No	

I hereby agree to take part in the above project (PRINT NAME)	
Signature of Participant	Date